PART 5

EXHIBITS TO DECLARATION OF SARAH BLAINE

frequency of about 30% in standard IVF. However, multiple pregnancy occurs less frequently with PGD because fewer embryos are generally transferred. We understand that preembryonic stage is an early stage of fertilized ovum development and occurs several days before implantation into the maternal uterus. At this early stage the embryo is relatively undifferentiated. Numerous animal studies and also human twin studies show that microsurgery of the oocyte and/or embryo, as described above, should not affect the normal development of the baby. However, since this procedure has been performed only in limited studies on human oocytes and embryos, its precise deleterious effects, if any, are unknown. In animal studies, there has been no apparent problem(s), and preliminary evidence with human embryos suggests that this will also be true. Therefore, because of the uncertainty of risks at present, it is not possible to describe the character and likelihood of the risks involved in microsurgery on the oocyte and/or embryo. The risks with IVF- embryo transfer procedures together with embryo microsurgery are also unknown but so far the clinical pregnancy rate for PGD at PIVF is greater than 30%. Although lower than the pregnancy rate for non-PGD IVF cycles, this is to be expected since with PGD only those embryos are transferred that will not develop the genetic disorder; genetically affected embryos capable of initiating a viable pregnancy must, nonetheless, be discarded.

2. We understand that because PGD is a new procedure, a major risk is that the procedure may not be successful. The genetic analysis may fail or be incorrect, although in PIVF's experience with 60+ patients to date, the accuracy has been greater than 90%. It is possible that a "normal" embryo may be incorrectly identified as "affected" and not transferred as a result. Conversely, we understand that an "affected" embryo may be incorrectly identified as "normal" leading to the possibility of an "affected" fetus and child. The other risks include genetic and developmental damage introduced during the procedure. However, we understand that, to detect such anomalies of the fetus, PIVF recommends that any PGD pregnancy be monitored very carefully by serial ultrasound examinations. In addition, requires that, at 10 weeks or 12-16 weeks respectively, chorionic villus sampling or amniocentesis (a collection of the fluid that surrounds the fetus) be performed to obtain for a comprehensive genetic analysis of amniotic fluid and cells. Finally, we understand that any abnormality of the fetus is identified or genetic disorders are detected by laboratory analysis, Dr. Grifo will discuss the implications of these findings with us in detail, and counsel us about our options.

We understand that, as patients undergoing preimplantation embryo testing, we must undergo an in vitro fertilization cycle and are not only responsible for the costs associated with this cycle but also PGD-related, supplemental costs. These costs include a PGD fee ($5000) that covers intracytoplasmic sperm injection and embryo biopsy. We understand that Dr. Marc Hughes will discuss with us the charges for the genetic diagnoses performed at Wayne State University; these charges (approximately $2000) include shipping costs for the biopsy specimens from PIVF to Michigan. We understand that the charges for FISH analysis at St. Barnabas Medical Center will range from $1500-$2500 depending on the analysis to be performed.

We understand that data from our IVF and PGD procedure must also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on us, the CDC has applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308 (d). This means that any information that the CDC has that identifies us will not be disclosed to anyone else without our consent. Thus, we understand that we cannot choose to have our information excluded and agree to provide PIVF with information regarding any future pregnancy, labor and delivery, and birth outcome resulting from the transfer of these cryopreserved embryos. We understand that it is important for us to remain in contact with PIVF; thus, we agree to advise PIVF promptly in writing of any change(s) in our mailing address or telephone number.

In summary, we understand that PGD will allow us to have a prenatal genetic diagnosis in hand prior to the establishment of pregnancy. This is a distinct advantage over the present methods, which would require us to

Initial: CRG-M mmg
Date: 6/04/04

wait until 9 to 16 weeks of pregnancy before determining if our fetus carries a genetic disorder. However, we understand that this PGD procedure is only specific for the particular genetic disorder that we have consulted Dr. Grifo for and not for all genetic disorders.

Chaya R Grossbaum-Morgenstern
Signature of Female Patient

Chaya R. Grossbaum-Morgenstern 6/04/04
Print Name and Date

Signature of Male Partner

Menachem M Grossbaum
Print Name and Date

Signature of Witness

Kaycee Brown
Print Witness Name and Date

This consent form must be signed by both the patient and her partner in the presence of a member of the clinical or nursing staffs at PIVF or in the presence of a notary public.

I have consulted with and explained the contents of this consent form to the patient and her partner. All question(s) concerning the procedures have been answered.

Signature of Physician

Print Physician Name and Date

CG092

Initial: CRM-G MMG
Date: 6/04/04

Preimplantation Genetic Diagnosis

Patient Informed Consent

Consent for Participation in Research Activities

Title of Project: Preimplantation Diagnosis for Families with High Genetic Risk

About this informed consent: An informed consent is really a *process* rather than just a form. . This is why we have spent considerable time with you discussing all of your reproductive options, not just those involving this research protocol. By now you should know that there are more conventionally accepted medical options to having a genetically unaffected baby. For personal reasons you have found these other "traditional" options unsatisfactory for your family and you are considering enrollment in the Preimplantation Genetic Diagnostic (PGD) program. From the information you have received, you should be familiar with both *in vitro* fertilization and the molecular diagnosis of the inherited disease in your family. You should understand that this is a research technology, and in no way should be construed as "routine" medical care. It is important that you feel comfortable with, and knowledgeable about, the information that we have given you concerning this research. Below is a summary of the most pertinent aspects of the PGD-IVF program. *You should feel free to ask any and all questions you have about it.* If you are undergoing the initial DNA testing or reproductive aspects of this process at a center distant from our program in Michigan, your doctors in genetics and reproductive medicine are logically your first source of information. However, we are available to assist you in understanding this process, so please call us if you have questions.

Overview: You are invited to participate in a research study. *In vitro* fertilization and embryo transfer is a routine procedure offered to infertile couples to assist them in obtaining a pregnancy. While you are not necessarily infertile, we know from prior genetic studies that the two of you have a high likelihood of bearing a child with a severe genetic disorder, and/or you have a member of your family who could potentially benefit from this research. Our research combines the technologies of *i) in vitro* fertilization (IVF); *ii)* micromanipulation and embryo biopsy; *iii)* genetic analysis of the biopsy material for potentially abnormal gene(s) and; *iv)* uterine transfer of the potentially normal embryo(s) to the donor mother. Biopsy is the process by which a single cell(s) is removed from the embryo for genetic analysis. Each of the steps involved in this protocol is outlined below.

Background Genetics: You are at a significantly increased risk of conceiving a child with a severe genetic disorder, or you have a child who could benefit from single cell DNA diagnostics. It is important that you understand that you have other reproductive options not involving this research protocol. You could elect not to have any (additional) children. Alternatively, adoption is a choice of many couples. Others choose artificial insemination or oocyte (egg) donation by an anonymous donor who has tested negative for the gene mutation. Many couples decide to assume the genetic risk, begin a pregnancy by natural means, and test prenatally by amniocentesis or chorionic villus sampling. You have received private counseling regarding these options.

If you elect to participate in this research project, it may be necessary for us to retest yo blood to confirm the genetic information you have as well as to see if our methods ca detect the particular genetic error in your family. Sometimes, the testing that has alread been performed for your family is not suitable for clinical use, and we need to repeat it an confirm the results. (***Please initial***)

Man **Woman**

MMG CRM-G I give permission for chromosome/DNA testing to be performed on me,

[and my minor child(ren) if medically appropriate], in order to identify o confirm the genetic information necessary to participate in this research study.

MMG CRM-G I understand that these genetic methods cannot predict all birth defects

or genetic disorders. The objective will be to test for just the specific inherited condition(s) involving my family.

In Vitro Fertilization: IVF has resulted in the birth of over a million babies around the world to couples who are otherwise infertile. While you are not necessarily infertile, most of these same medical techniques and procedures will be used in obtaining the eggs and fertilizing them outside of the body. You have received personal reproductive counseling by your physician(s), and again by the IVF counselor-coordinator. IVF itself is not considered "research" since it is in routine practice throughout the world. However, there are risks involved that are important for you to understand. You have read, been counseled, asked any questions you might have, and signed the Consent Form(s) pertaining to (***Please initial***:

Man **Woman**

MMG CRM-G Disclosure and Consent to *In Vitro* Fertilization and embryo transfer

(or similar such document at your clinic)

MMG CRM-G Disclosure and Consent for embryo cryopreservation (freezing)

(or similar such document at your clinic; if appropriate)

When ovarian stimulation is complete her eggs will be retrieved by transvaginal ultrasound and described on the separate IVF consent form. The retrieved eggs are then inspected and graded prior to insemination with the man's sperm. The laboratory procedures are state-of-the-art and subject to modification at the discretion of the IVF team to improve the likelihood of pregnancy.

Biopsy of the Pre-embryo: The experimental portion of this research project begins at this step. Approximately three days after fertilization, a biopsy will be performed with the removal by micromanipulation of one or two cells (blastomeres) from the 4-8 cell embryo. After the micromanipulation, the embryos will either be returned to culture or frozen to allow in-depth genetic analysis of the biopsied cell(s). The genetic findings from this research

study is combined with information regarding the embryology (the quality of the dividing cells), and then you and your Reproductive Endocrinologist(s) decide which, if any, of the embryos will be transferred to the uterus to begin the pregnancy. Embryos that have are not genetically or morphologically suitable for uterine transfer are not transferred.

Many families who have undergone this process before you have donated their unused embryos in order for your doctors to develop new DNA/chromosome tests which, in turn, help other couples. If you choose to donate your untransferred embryos to research, they will not be further grown as embryos and they will not be given to any other patient. Your doctors will use them in an ethically responsible way to understand more about the disease in your family and to develop new PGD tests to assist future families needing this technology. Untransferred embryos that are not cryopreserved for us will be: (***Please initial your choice***)

Wife	**Husband**	
CRMG	[illegible]	Used for research purposes at the discretion of the investigator, to understand the molecular basis of inherited birth defects and to assist in the development of PGD testing on other diseases for other families.
CRMG	[illegible]	Allowed to dissolve in culture and be discarded.

Background Information on the Risks Involved: The post fertilization time period is an early stage in embryo development, before it has implanted into the mother's uterus. At this early stage the embryo is relatively undifferentiated. This means that the cells seem to have identical potential to ultimately become the placenta, membranes, fetus or any organ system. Numerous animal studies and also human twin studies have shown that the microsurgery of the embryo does not seem to affect the normal development of the baby. This biopsy procedure has been performed on embryos at centers in the United States and around the world beginning in 1991. Currently, the combination of the biopsy procedure with genetic testing can identify some of the characteristics that would lead to birth defects and genetic disease. However, since this is a relatively new procedure, the success rate of identifying these problems is unclear. Thus far, there is no evidence that deleterious effects have occurred from the biopsy process. At present, we are uncertain of all of the potential risks that could occur as a result of the microsurgery.

In order to monitor the success rates of this technology, you agree that between ten and fifteen weeks of pregnancy you will undergo conventional prenatal genetic testing in the form of chorionic villus sampling (CVS) or amniocentesis. The sample will be used to confirm the predicted PGD test results. If any abnormality of the fetus is identified, or risk of genetic disorder is recognized, the implications of these findings will be discussed with you in detail.

Specific Points Regarding Participation in this Research Project

This research protocol carries some potential risks. Below is a list of specific points pertaining to these procedures. Only those three marked with an asterisk (numbers 1, 5 and 6) are new to the preimplantation genetics protocol. The remaining points pertain to standard IVF, should also be part of your separate consent form(s) pertaining to the IVF procedures, and are included here for completeness:

1. *The purpose of this procedure is for us to obtain a pregnancy and to have a child that does not have the severe genetic disease for which we are at high risk, and/or to assist a child we have currently that could benefit from this research procedure via cord blood transplantation;

2. We will be enrolled in standard IVF protocols as conducted by our reproductive endocinologists and embryologists. The normal and high standards of care in this medical setting will be used. We have read and understand the risks and benefits of ovulation-induction as outlined on a separate consent form(s);

3. If pregnancy occurs, there is a risk of multiple gestation (multiple fetuses), miscarriage, ectopic pregnancy such as in the fallopian tube requiring further treatment, and abnormalities in the fetus/child such as, but not limited to, congenital anomalies or embryonic/fetal death or stillbirth;

4. Fertilization may fail to occur, the embryos may fail to develop or grow, or the growth may be abnormal;

5. *A laboratory or transportation accident may result in loss or damage to the egg, sperm or embryos. Specific data provided to us by others prior to your testing could be inaccurate, leading potentially to a misdiagnosis. The specific genetic test used in this PGD protocol may fail to diagnose correctly the embryo as having (or not having) the DNA/Chromosome abnormality or molecular markers of interest.

6. *The genetic testing will be performed on a single cell. This pushes the molecular technology to its theoretical and practical limits. This research is relatively new and not widely available. There is a possibility that a misdiagnosis may be made on any one of the embryos prior to uterine transfer, or that the actual process of testing may adversely affect the development of the fetus;

7. Any or all of the embryo(s) may not survive freezing or thawing if cryopreserved;

8. The pregnancy may not be normal even if implantation occurs in the uterus. There is a risk for loss of the fetus or neonate, and there is an unknown risk for congenital abnormalities or other problems with the newborn.

Confidentiality.

You should understand every effort will be made to maintain the confidentiality of yo medical records and research material within legal limits; however, absolute confidentiali cannot be guaranteed. You also understand that your names and other information tha could be associated with your family will not be disclosed without your expressed writte consent. It will be necessary for the doctors and scientists involved directly in your care t exchange medical information about you, and you will have the opportunity to approve c deny this exchange of material. Data generated within the PGD program will be presente in scientific format with your anonymity maintained, unless you authorize otherwise i writing.

Risk & Injury.

IN THE EVENT OF INJURY RESULTING FROM THIS RESEARCH, THE UNIVERSITY AND/OR THE DETROIT MEDICAL CENTER, ARE NOT ABLE TO OFFER FINANCIAL COMPENSATION NOR ABSORB THE COSTS OF YOUR MEDICAL TREATMENT. HOWEVER, NECESSARY FACILITIES, EMERGENCY TREATMENT AND PROFESSIONAL SERVICES WILL BE AVAILABLE TO RESEARCH SUBJECTS, JUST AS THEY ARE TO THE COMMUNITY GENERALLY. MY SIGNATURE BELOW ACKNOWLEDGES MY VOLUNTARY PARTICIPATION IN THIS RESEARCH PROJECT, BUT IN NO WAY RELEASES THE INVESTIGATORS FROM THEIR PROFESSIONAL AND ETHICAL RESPONSIBILITY TO ME.

Final Comments.

If you have undergone or will be undergoing diagnostic and therapeutic care (DNA/chromosome testing, reproductive care etc) at another institution (University, Clinic, Hospital, Company) not formally affiliated with Wayne State University, it is likely that you will have a separate consent form pertaining to that institution. This Informed Consent does not supercede or replace the one you accept from that/those institution(s).

You understand that your participation in this procedure is voluntary and that your refusal to participate will involve no penalty or loss of benefits to which you would otherwise be entitled. If you agree to participate, you (or your legal representative) may change your mind about participating at any time.

You understand that your signature indicates that you have read and understand the above information. You have discussed this procedure in detail with the Principle Investigator or your geneticist and/or genetic counselor, and your reproductive endocrinologist/gynecologist. Your signature below indicates that you wish to have your oocytes fertilized for the purpose of preimplantation genetic analysis.

If you have any additional questions later, you can contact any of your doctors.

Chyn K Gross 6/04/04 — 6/4/04

Woman's Signature — Date — Man's Signature — Date

6/4/04

Principal Investigator — Date — Witness — Date

Informed Con to Perform an HIV Test

New York State Department of Health
AIDS Institute

ne decision to have an HIV test is voluntary. In order to have an HIV test in New York State, you must give your consent in writing on the bottom of this form.

Testing for HIV Infection

Testing Methods:

There are a number of tests that can be done to show if you are infected with HIV, the virus that causes AIDS. Your provider or counselor can provide specific information on these tests. These tests involve collecting and testing blood, urine or oral fluid. The most common test for HIV is the HIV antibody test.

Meaning of HIV Test Results:

- A negative result on the HIV antibody test most likely means that you are not infected with HIV, but it may not show recent infection. If you think you have been exposed to HIV, you should take the test again three months after the last possible exposure.
- A positive result on the test means that you are infected with HIV and can infect others.
- Sometimes the HIV antibody test result is not clearly positive or negative, or may be a preliminary result. Your provider or counselor will explain this result, and may ask that you give your consent for further testing.

Confidential or Anonymous HIV Testing:

When you decide to have an HIV antibody test, you may choose either a confidential or an anonymous test.

- If you want your test result to become part of your medical record so it can be used for your medical care, you can have a confidential test done. A confidential test requires that you provide your name.
- If you do not want anyone to know your test results or that you were tested, you can have an anonymous test at an anonymous test site. You will not be asked your name, address or any other identifying information.
- If you receive an HIV positive test result at an anonymous test site approved by the NYS Department of Health, you will have the option of changing your test result to confidential by attaching your name to the test result. This will allow your test result to become part of your medical record.

Benefits to Testing:

There are many benefits to having an HIV test and knowing if you are infected.

If you receive an HIV negative test result:

- Your provider or counselor will tell you how to protect yourself from getting infected with HIV in the future.

If you receive an HIV positive test result:

- Your provider can give you medical care and treatment that can help you stay healthy and can manage your HIV illness.
- Your provider or counselor can tell you how to prevent passing the virus to your sexual or needle sharing partners.
- You can increase your chances of staying healthy by eating a well-balanced, nutritious diet, getting enough sleep, exercising, avoiding alcohol, tobacco, and recreational drugs, reducing stress and having regular check-ups.

If you are a woman who receives an HIV positive test result:

- If you are thinking about having a child, your provider will give you information to help you make informed choices about your health care and pregnancy.
- If you are pregnant, your doctor can provide the care you need and information about services and options available to you. Your provider can tell you about the risks of passing HIV infection to your baby, about medications given during pregnancy that can significantly reduce the risk of passing HIV to your baby, and the medical care available for babies who may be infected with HIV.
- If you have given birth to or breast fed a child since you were infected, your child will need to be tested for HIV and, if infected, may need additional care and treatment. Your provider can give you information about medical care available for children who may be infected with HIV.

genesis
genetics institute

Printed Family Name: GROSSBAUM, CHAYA

HIPPA Participant Authorization

Our Commitment to the Privacy & Security of Your Health Information

We are dedicated to assisting you in your medical care, and we are also deeply committed to maintaining your privacy. During the course of your treatment(s) in this Preimplantation Genetic Diagnosis (PGD) protocol, it will be important for us to discuss and exchange certain personal information about you with other members of your health care team. This information is called your Protected Health Information (PHI). Because these individuals (for example, your geneticist, genetic counselor, IVF center, PGD doctors/scientists, transplantation team) are often at different institutions/states/countries, we need your permission beforehand in order to participate in these medical and scientific discussions about you. Nonetheless, each individual on your health care team does not need to know or have access to everything. We believe in a minimal "need-to-know" approach to the exchange of your health information.

Doctors have exchanged this sort of information for years in the practice of medicine. However, in this day of electronic databases, there is (rightfully) concern about how private health information about you is collected and shared. For that reason, we applaud the fact that the US Federal Government has now issued a regulation to provide safeguards for the privacy and security of health information that may identify you. This rule was issued under a law called the Health Insurance Portability and Accountability Act (HIPPA). This document that you are now reading, is called a "Participant Authorization," and it describes your rights and explains how your health information will be used and disclosed during your care.

Section A: Protocol Information

Protocol Title:	Molecular & Cytogenetic Testing of Human Pre-embryos for Genetic Disease
Principal Investigator:	Mark R. Hughes, MD, PhD
Address:	The Genesis Genetics Institute The Charles Trowbridge Historical House 1380 East Jefferson Avenue Detroit, MI 48207
Phone & Fax	313-544-4006

You have agreed to participate in this research study and you have signed a separated "Informed Consent" that explains the procedures, the risks and the benefits of this protocol. This Authorization Form gives more detailed information about how your health information will be protected. By signing this document you are permitting The Genesis Genetics Institute to use your Protected Health Information (PHI) for research purposes and in your health care. You are also allowing us to exchange PHI with other members of your medical team at outside organizations

Section B: Protected Health Information

1. **What PHI is collected and might be shared amongst your medical team?**
The following PHI items that have been checked below will be collected, used for research and may be disclosed or released during your involvement in this research project:

- ☒ Your names and potentially the names of your child(ren)
- ☒ Your Address, Telephone Numbers, E-mail Address.
- ☒ Dates (e.g. birth, menstrual cycle, IVF-related dates, delivery date)
- ☐ Biometric Identifiers (e.g. photograph, finger print, voice print)
- ☒ Identifying Number (e.g. clinic, protocol, insurance, social security, medical record)
- ☒ Genetic mutation, marker, polymorphism data, and your family genetic history

2. **Why is this information needed?**
This information is important to your health care providers and members of the research team in order to contact you during this protocol, as part of this research project, and in your treatment.

3. **Which project personnel may use or disclose your PHI?**
The following individuals and organizations may use or disclose your PHI for <u>THIS</u> protocol <u>ONLY</u>.

- The Principal Investigator, Dr. Hughes, and key personnel at Genesis Genetics who are involved in this protocol and in your care. This is limited to individuals who require access in the performance of their duties (for example: to provide treatment, to ensure integrity of the data, accounting or billing matters, etc).
- Collaborating health care professionals (e.g. your reproductive endocrinologist, embryologist, nurse coordinator, genetic counselor, molecular biologist/laboratory that found the gene mutaton in your family, transplantation physician, geneticist, etc).
- The Human Investigation Committee and the Institutional Review Boards of the Genesis Genetics Institute and the University, and at your clinic at a collaborating institution(s). (These Boards oversee research protocols and protect patient interests. They generally do not request any of your information unless there is a concern about the protocol or about your well being. Since your health care providers are at different universities/organizations, each one may have separate committees and boards, and (sorry), more forms like this one.)
- Your health insurance company, but only if we receive <u>separate, written, and prior authorization</u> from you to release any PHI to them.

4. **Can you change your mind?**
You may withdraw your permission for the use and disclosure of your PHI at any time, but you must do so in writing to the Principal Investigator at the address on the first page of this form. After receiving the request to withdraw from the protocol, you will be contacted concerning a plan for your withdrawl from the protocol. Even if you withdraw your permission, you also are withdrawn from the research protocol. The Principal Investigator may still use your PHI that was collected prior to your written request, if that information is necessary to the integrity of the study.

You will be given a copy of this Participant Authorization Form, describing your confidentiality and privacy rights for this study. By signing this document you are authorizing the collection and potential exchange of this information described above.

Chaya R. Grossbaum Printed Woman's Name	Chaya R. Grossbaum Woman's Signature	7/14/04 Date
Menachem M Grossbaum Printed Man's Name	Man's Signature	7/14/04 Date

CG101

H#: 6902 Consent Version Date: 11/17/03

Office of Institutional Board of Research Associates
NYU School of Medicine
550 First Ave. Building #VET
10 West
NY, NY 10016
Phone: 212.263.4110
Fax: 212.263.4147

Principal Investigator: James A. Grifo, M.D., Ph.D.

INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

TITLE OF RESEARCH: RESEARCH STUDIES ON DISCARDED IVF TISSUES

A. PURPOSE OF THE STUDY:

In vitro fertilization (IVF) involves the fertilization of oocytes (eggs) by sperm in a culture dish in the laboratory. You are being asked to volunteer discarded materials (fluids, granulose cells, sperm, eggs, embryos) from your IVF cycle for use in a research study. This consent/authorization form includes information about this study.

In order to understand the biology how the human egg and sperm mature and how the early human embryo develops it is best to use human rather than animal tissues. Human tissues are also most appropriate when developing and assessing the safety of new procedures for the IVF laboratories, procedures used to culture, micromanipulate (handle an individual cell) and cryopreserve (freeze-thaw) eggs and embryos. During your IVF cycle, biologic specimens will often be discarded because they are either a procedural by-product (blood, follicle fluids, granulosa cells, excess sperm) or an abnormal result (immature oocytes, abnormally fertilized eggs, poor quality embryos unsuitable for transfer to the uterus or cryopreservation). The discarding of these fluids, cells and tissues differs from patient to patient. Although blood, follicle fluid, granulosa cells and sperm are routinely discarded from patients, we cannot predict whether a patient will or will not have immature eggs, abnormally fertilized eggs or poor quality embryos to discard. Thus, we are now seeking your consent to conduct these research studies should these discard materials be available.

The discarded materials will be used in many research studies. Discarded blood, follicle fluid, culture media and granulosa cell specimens are monitored to examine how ovarian hormones and growth factors influence egg development and whether they are secreted differently with different ovarian stimulation treatments. Discarded sperm, eggs and embryos are used to develop new laboratory micromanipulation techniques, freezing / thawing procedures and culture protocols. These cells and tissues are also used to assess cell levels of molecules that regulate how the egg matures, when the embryonic cells divide and whether they differentiate to develop into the fetus or the placenta. Finally, these discarded cells and tissues are used to develop and perform genetic testing procedures that determine if abnormalities in chromosome number or gene expression are associated with any of these new techniques or with a naturally occurring failure(s) of an embryo to develop normally.

 Subject's Initials: CRG-M mmg Date: 7/19/04 7/19/04

(IRB Official Use Only)
This Consent Document is approved for use by the New York University's Institutional Review Board (IRB).
Only the IBRA-stamped approved form may be used.

Approved: From: 12/22/2003 *To:* 12/21/2004
The study expiration date applies for this form
Template rev. date: 3/23/03
IRB consent - Research on discarded IVF tissues - 11-24-03.doc

NYUSOM IRB APPROVED

CG102

H#: 6902

Consent Version Date: 11/17/03

Office of Institutional Board of Research Associates
NYU School of Medicine

Your decision as to whether or not to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled.

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.

Your decision as to whether to give your Authorization for the use and disclosure of your protected health information for this study is also completely voluntary; however, if you decline to give your Authorization or if you withdraw your Authorization you may not participate in the study.

K. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:

If you agree to allow your blood, follicular fluids, granulose cells, eggs, sperm and embryos to be kept for research, you are free to change your mind at any time. We ask that you contact Dr. James A. Grifo in writing and let him know you are withdrawing your permission for your blood, follicular fluids, granulose cells, eggs, sperm and embryos to be used for research. His mailing address is Program for IVF, 660 First Ave (5th Fl), New York, NY 10016. Any unused blood, follicular fluids, granulose cells, eggs, sperm and embryos will be discarded.

L. CONTACT PERSON(S):

For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Administrator, Institutional Board of Research Associates, Telephone No. 212-263-4110.

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study drug or procedure, please contact the Principal Investigator Dr. James A. Grifo at the following telephone number 212-263-8990.

AGREEMENT TO PARTICIPATE AND AUTHORIZATION FOR THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION:

Part of the consent process includes your Authorization to use Protected Health Information for the purposes of this study, as described above. If you do not want to authorize the use of this PHI, you should not agree to be in this study.

☐ I have read this consent form or ☐ it was read to me by: _____.

Any questions I had were answered by: _____.

I ☐ am ☐ am not participating in another research project at this time.
(If yes, you should discuss this with your study doctor.)

Subject's Initials: CRG MMG Date: 7/19/04 7/19/04

(IRB Official Use Only)
This Consent Document is approved for use by the New York University's Institutional Review Board (IRB).
Only the IBRA-stamped approved form may be used.

Approved: From: 12/22/2003 *To:* 12/21/2004
The study expiration date applies for this form
Template rev. date: 3/23/03
IRB consent - Research on discarded IVF tissues - 11-24-03.doc

NYUSOM
IRB APPROVED

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 800.631.1390

PATIENT INFORMATION
ROSSBAUM-MORGENSTEN,CHAYA RAC

DOB:
GENDER: F
Age: 23
SS:
ID:
PHONE:

REPORT STATUS Final

ORDERING PHYSICIAN
LICCIARDI,FRED

CLIENT INFORMATION
22494
NYUMC PIVF
660 FIRST AVENUE
NEW YORK, NY 10016-3295

SPECIMEN INFORMATION
SPECIMEN: 33032908
REQUISITION: A02615025743A
LAB REF NO:

COLLECTED: 04/19/2004 08:50
RECEIVED: 04/20/2004 00:52
REPORTED: 04/20/2004 17:06

Test Name	In Range	Out of Range	Reference Range	Lab
HIV-1/HIV-2 AB SCR W/RFX HIV-1 & HIV-2 AB	Nonreactive		Nonreactive	TBR

Government regulations require the assurance of patient confidentiality.

Performing Laboratory Information:

TBR Quest Diagnostics One Malcolm Avenue Teterboro NJ 07608 Laboratory Director: William E. Tarr, M.D.

Date: Tue, 11 May 2004 08:44:29 -0400
From: Mark Hughes <pgd@GenesisGenetics.org>
To: griolf01@med.nyu.edu
Reply-to: pgd@GenesisGenetics.org
Subject: RE: Morgenstern-Grossbaum.CF10+11.NYU.2004#316

Yes-
Just remember that we are closed from June 27-July 11, so last day for biopsy is June 25th.
Other than that, we're set.
Let us know when you think retrieval might be.
Thx

-----Original Message-----
From: griolf01@med.nyu.edu [mailto:griolf01@med.nyu.edu]
Sent: Monday, May 10, 2004 4:43 PM
To: pgd@genesisgenetics.org
Subject: Fwd: Morgenstern-Grossbaum.CF10+11.NYU.2004#316

good afternoon dr hughes
imelda would like to know if they are ready
to start
please advise
thanks

This mail sent through IMP: http://horde.org/imp/

CG105

genzyme
GENETICS

Cystic Fibrosis Mutation Analysis

Patient Name: Grossbaum-Morgenstern, Chaya Rochel
Referring Physician: Frederick L. Licciardi, M.D.
Specimen #: 60317586 **Client #:**
Patient ID: **Case #:**

DOB:
Sex: F
SSN:

Date Collected: 04/19/2004
Date Received: 04/20/2004
Lab ID:
Hospital ID:
Specimen Type: BLDPER

Program for IVF (Non-Donor)
New York University Medical Center
660 1st Avenue
5th Floor
New York NY 10016

Ethnicity: Ashkenazi Jewish

Indication: Carrier test / No family history

RESULTS: POSITIVE for one copy of the G542X mutation

INTERPRETATION

This individual is a carrier of CF.

COMMENTS:

Genetic counseling is recommended to discuss the potential clinical and/or reproductive implications of this result, as well as recommendations for testing other family members and, when applicable, this individual's partner.

Mutation Detection Rates among Ethnic Groups Detection rates are based on mutation frequencies in patients affected with cystic fibrosis. Among individuals with an atypical or mild presentation (e.g. congenital absence of the vas deferens, pancreatitis) detection rates may vary from those provided here.

Ethnicity	Detection rate	References
Caucasian	92.6%	Genet in Med 3:168, 2001 in conjunction with Genet in Med 4:90, 2002
African American	81%	Genet in Med 3:168, 2001
Hispanic	72%	Genet in Med 3:168, 2001
Ashkenazi Jewish	97%	Am J Hum Genet 51:951, 1994
Jewish, non-Ashkenazi	Varies by country of origin	Genet Testing 5:47, 2001, Genet Testing, 1:35, 1997
Asian	Not Provided	Insufficient data
Other or Mixed Ethnicity	Not Provided	Detection rate not determined and varies with ethnicity

This interpretation is based on the clinical information provided and the current understanding of the molecular genetics of this condition. Although DNA-based testing is highly accurate, rare diagnostic errors may occur. Examples include misinterpretation because of genetic variants, blood transfusion bone marrow transplantation, or erroneous representation of family relationships or contamination of a fetal sample with maternal cells.

METHOD

DNA is isolated from the sample and tested for the 83 CF mutations listed. Regions of the CFTR gene are amplified enzymatically and hybridized to specific CF mutation oligonucleotide probes. Results are characterized as positive or negative, and specimens with positive results are tested for specific mutation identity. The assay discriminates between ΔF508 and the following polymorphisms: F508C, I506V, I506M and 507V.

Under the direction of: Ruth A Helm

Ruth A. Helm, Ph D.

Date: 04/30/2004

Testing Performed At Genzyme Genetics 3400 Computer Drive Westborough, MA 01581 1-800-255-7357

CG106

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 800.631.1390

SPECIMEN INFORMATION
SPECIMEN: 28115758
REQUISITION: T224940002094

COLLECTED: 03/30/2004 15:39
RECEIVED: 03/31/2004 02:28
REPORTED: 04/08/2004 13:44

PATIENT INFORMATION
GROSSBAUM,CHAYA

DOB: AGE: 23
GENDER: F
SS:

PHONE:

REPORT STATUS FINAL

ORDERING PHYSICIAN
FREDERICK,LICCIARDI

CLIENT INFORMATION
T22494 10270350
NYUMC PIVF
660 FIRST AVENUE
NEW YORK, NY 10016-3295

Test Name	In Range	Out of Range	Reference Range	Lab
TSH See footnote 1	1.83		0.40-5.50 mIU/L	TBR
PROLACTIN	7.3		ng/mL Reference Range Female Postmenopausal: 2-20 Pregnant: 10-209 Non-pregnant: 3-30	TBR
HB S AG W/REFLEX CONF HB S AG	0.33	Negative	0.0 - 0.79 Ratio	TBR
HCV AB Interpretation:	0.18	Negative	0.0-1.0 Ratio	TBR
VDRL SERUM			Nonreactive	TBR

Effective August 1, 2000 the VDRL,SERUM test will be discontinued. When serum VDRL is ordered, test 1156F, RPR w/Titer & Confirmation Reflex will automatically be performed. Positive RPR results will be titered and confirmed by FTA. Please note that syphilis serology on CSF samples will continue to be performed by VDRL. For questions, please call (800)222-0446 ext. 6339 or ext. 5752.

VZV AB (IGG),EIA	3.28	H	0.00-0.90 I.S.R.	TBR

Interpretation: Positive or Immune

Varicella Zoster IgG, EIA reliably measures immunity due to previous infection, but is unsuitable for detection of post-vaccination immune status.

RUBELLA AB (IGG)	2.04	H	0.00-0.90 I.S.R.	TBR

Interpretation: Positive or Immune

Quest On Demand™

QUEST DIAGNOSTICS INCORPORATED

REPORTED: 04/08/2004 13:44

PATIENT INFORMATION
GROSSBAUM, CHAYA

DOB: AGE: 23
GENDER: F

REPORT STATUS FINAL

ORDERING PHYSICIAN
FREDERICK, LICCIARDI

Test Name	In Range	Out of Range	Reference Range	Lab
CHLAMYDIA/GC DNA W/REFLEX				
CHLAMYDIA/GC DNA DUAL SCN	Negative		Negative	TBR
BLOOD GROUP & RH				
BLOOD GROUP	O			TBR
RH TYPE	Positive			
ANTIBODY SCREEN, RBC W/RFX				
ANTIBODY SCREEN	Negative		Negative	TBR

This test is intended as a screen to detect those IgG antibodies implicated in hemolytic diseases of the newborn. It does not routinely detect IgM antibodies and thus is not suitable for screening for irregular antibodies prior to transfusion.

FOOTNOTE(S):

1 TSH REFERENCE RANGE:
For Pregnant Patients:

First Trimester	0.30-4.50 mIU/L
Second Trimester	0.50-4.60 mIU/L
Third Trimester	0.80-5.20 mIU/L

PERFORMING LABORATORY INFORMATION:

BR Quest Diagnostics One Malcolm Avenue Teterboro NJ 07608 Laboratory Director: William E. Tarr, M.D.
CLIA No: 31D0696246

Quest Diagnostics®

QUEST DIAGNOSTICS INCORPORATED

REPORTED: 04/02/2004 08:26

PATIENT INFORMATION
GROSSBAUM, CHAYA

DOB: [redacted] AGE: 23
GENDER: F

REPORT STATUS PARTIAL

ORDERING PHYSICIAN
FREDERICK, LICCIARDI

Test Name	In Range	Out of Range	Reference Range	Lab
ANTIBODY SCREEN, RBC W/RFX				
ANTIBODY SCREEN	Negative		Negative	TBR

This test is intended as a screen to detect those IgG antibodies implicated in hemolytic diseases of the newborn. It does not routinely detect IgM antibodies and thus is not suitable for screening for irregular antibodies prior to transfusion.

FOOTNOTE(S):

1 TSH REFERENCE RANGE:
For Pregnant Patients:

First Trimester	0.30-4.50 mIU/L
Second Trimester	0.50-4.60 mIU/L
Third Trimester	0.80-5.20 mIU/L

PERFORMING LABORATORY INFORMATION:

TBR Quest Diagnostics One Malcolm Avenue Teterboro NJ 07608 Laboratory Director: William E. Tarr, M.D.
CLIA No: 31D0696246

PARTIAL REPORT

Quest Diagnostics®

Quest On Demand™

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 800.631.1390

PATIENT INFORMATION
GROSSBAUM, CHAYA

DOB AGE: 23
GENDER: F
SS:

PHONE:

REPORT STATUS FINAL

ORDERING PHYSICIAN
FREDERICK, LICCIARDI

CLIENT INFORMATION
T22494 10270350
NYUMC PIVF
660 FIRST AVENUE
NEW YORK, NY 10016-3295

SPECIMEN INFORMATION
SPECIMEN: 28115758
REQUISITION: T224940002094

COLLECTED: 03/30/2004 15:39
RECEIVED: 03/31/2004 02:28
REPORTED: 03/31/2004 17:20

Test Name	In Range	Out of Range	Reference Range	Lab
TSH See footnote 1	1.83		0.40-5.50 mIU/L	TBR
PROLACTIN	7.3		ng/mL	TBR

AL

Reference Range
Female
Postmenopausal: 2-20
Pregnant: 10-209
Non-pregnant: 3-30

VZV AB (IGG),EIA	3.28	H	0.00-0.90 I.S.R.	TBR

Interpretation: Positive or Immune

Varicella Zoster IgG, EIA reliably measures immunity due to previous infection, but is unsuitable for detection of post-vaccination immune status.

RUBELLA AB (IGG)	2.04	H	0.00-0.90 I.S.R.	TBR

Interpretation: Positive or Immune

CHLAMYDIA/GC DNA W/REFLEX CHLAMYDIA/GC DNA DUAL SCN	Negative	Negative	TBR
BLOOD GROUP & RH BLOOD GROUP RH TYPE	O Positive		TBR
ANTIBODY SCREEN,RBC W/RFX ANTIBODY SCREEN	Negative	Negative	TBR

This test is intended as a screen to detect those IgG antibodies implicated in hemolytic diseases of the newborn. It does not routinely detect IgM antibodies and thus is not suitable for screening for irregular antibodies prior to transfusion.

Quest Diagnostics®

Quest on Demand™

Chavga

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 800.631.1390

PATIENT INFORMATION
GROSSBAUM,MENACHEM MENDEL

DOB:
GENDER: M
SS:
ID:
PHONE:
AGE: 24

REPORT STATUS FINAL

ORDERING PHYSICIAN
LICCIARDI, FRED

CLIENT INFORMATION
T22494
NYUMC PIVF
660 FIRST AVENUE
NEW YORK, NY 10016-3295

'ECIMEN INFORMATION
SPECIMEN: 28115725
REQUISITION: A02615025465A

10270350

COLLECTED: 03/30/2004 15:42
RECEIVED: 03/31/2004 02:25
REPORTED: 03/31/2004 17:20

Test Name	In Range	Out of Range	Reference Range	Lab
HB S AG W/REFLEX CONF				
HB S AG	0.26	Negative	0.0 - 0.79 Ratio	TBR
HCV AB	0.22		0.0-1.0 Ratio	TBR
Interpretation:		Negative		
RPR W/TITER & CONF RFX				
RPR SCREEN	Nonreactive		Nonreactive	TBR
HIV-1/HIV-2 AB SCR W/RFX				
HIV-1 & HIV-2 AB	Nonreactive		Nonreactive	TBR
See footnote 1				

FOOTNOTE(S):
1

Government regulations require the assurance of patient confidentiality.

PERFORMING LABORATORY INFORMATION:
TBR Quest Diagnostics One Malcolm Avenue Teterboro NJ 07608 Laboratory Director: William E. Tarr, M.D.
CLIA No: 31D0696246

NL

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 800.631.1390

SPECIMEN INFORMATION
SPECIMEN: 28115758
REQUISITION: T224940002094
LAB REF NO:

COLLECTED: 03/30/2004 15:39
RECEIVED: 03/31/2004 02:28
REPORTED: 03/31/2004 08:24

PATIENT INFORMATION
GROSSBAUM,CHAYA

DOB: Age: 23
GENDER: F
SS:

PHONE:

EPORT STATUS **Partial**

ORDERING PHYSICIAN
FREDERICK,LICCIARDI

CLIENT INFORMATION
22494
NYUMC PIVF
660 FIRST AVENUE
NEW YORK, NY 10016-3295

Test Name	In Range	Out of Range	Reference Range	Lab
TSH	1.83		0.40-5.50 mIU/L	TBR
		TSH REFERENCE RANGE:		
		For Pregnant Patients:		
		First Trimester	0.30-4.50 mIU/L	
		Second Trimester	0.50-4.60 mIU/L	
		Third Trimester	0.80-5.20 mIU/L	
PROLACTIN	7.3		ng/mL	TBR
			Reference Range	
			Female	
			Postmenopausal: 2-20	
			Pregnant: 10-209	
			Non-pregnant: 3-30	
VZV AB (IGG),EIA	Pending			
RUBELLA AB (IGG)	Pending			
CHLAMYDIA/GC DNA W/REFLEX				
CHLAMYDIA/GC DNA DUAL SCN	Pending			
BLOOD GRP,RH & AB SCREEN				
BLOOD GROUP & RH				
BLOOD GROUP	O			TBR
RH TYPE	Positive			
ANTIBODY SCREEN,RBC W/RFX				
ANTIBODY SCREEN	Negative		Negative	TBR

This test is intended as a screen to detect those IgG antibodies implicated in hemolytic diseases of the newborn. It does not routinely detect IgM antibodies and thus is not suitable for screening for irregular antibodies prior to transfusion.

Performing Laboratory Information:

TBR Quest Diagnostics One Malcolm Avenue Teterboro NJ 07608 Laboratory Director: William E. Tarr, M.D.

PATIENT INFORMATION
GROSSBAUM,MENACHEM MENDEL

EPORT STATUS **Partial**

QUEST DIAGNOSTICS INCORPORATED
CLIENT SERVICE 800.631.1390

DOB: Age: 24
GENDER: M

ORDERING PHYSICIAN
LICCIARDI,FRED

PECIMEN INFORMATION
SPECIMEN: 28115725
REQUISITION: A02615025465A
LAB REF NO:

ID:
PHONE:

CLIENT INFORMATION
22494
NYUMC PIVF
660 FIRST AVENUE
NEW YORK, NY 10016-3295

COLLECTED: 03/30/2004 15:42
RECEIVED: 03/31/2004 02:25
REPORTED: 03/31/2004 07:23

Test Name	In Range	Out of Range	Reference Range	Lab
RPR/HBsAg/HCV/HIV-1/HIV-2 ABSCN				
HB S AG W/REFLEX CONF				
HB S AG	Pending			
HCV AB	Pending			
RPR W/TITER & CONF RFX				
RPR SCREEN	Nonreactive		Nonreactive	TBR
HIV-1/HIV-2 AB SCR W/RFX				
HIV-1 & HIV-2 AB	Pending			

Performing Laboratory Information:

BR Quest Diagnostics One Malcolm Avenue Teterboro NJ 07608 Laboratory Director: William E. Tarr, M.D.

THIS SPECIMEN WAS REVIEWED AS PART OF OUR QUALITY CONTROL PROGRAM.

DIANON SYSTEMS

Department of GYN Pathology

KK4JKYT DIAGNOSTIC REPORT

KUCHERA & KUCHERA, MDS
160 HANOVER AVE

CEDAR KNOLLS, NJ 07927

Accession No.	Chart No.	Sex	D.O.B.	Page
JD3092817		F	23 Yrs	1 of 1

Patient Name: MORGENSTERN, CHAYA (149704228)	Collected: 08/04/03
Requesting Physician: KUCHERA, JAMES, MD	Received: 08/05/03
Referring Physician:	Reported: 08/08/03
Clinical Data: L.M.P.: 07/03/2003;	

PATHOLOGY CONSULTATION

SPECIMEN: ThinPrep Pap Test, 1 vial received

SPECIMEN SOURCE:
Cervix

SPECIMEN ADEQUACY:
SATISFACTORY FOR EVALUATION. ENDOCERVICAL/TRANSFORMATION ZONE COMPONENT PRESENT.

DIAGNOSIS:
NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY.

CYTOLOGY HISTORY

	08/04/03
MALIGNANT	
HGSIL	
LGSIL	
ASC/AGC	
NEGATIVE	92817
UNSATISFACTORY	

X-Performed Outside of DIANON. 01234-DIANON Acc. Number

COMMENTS

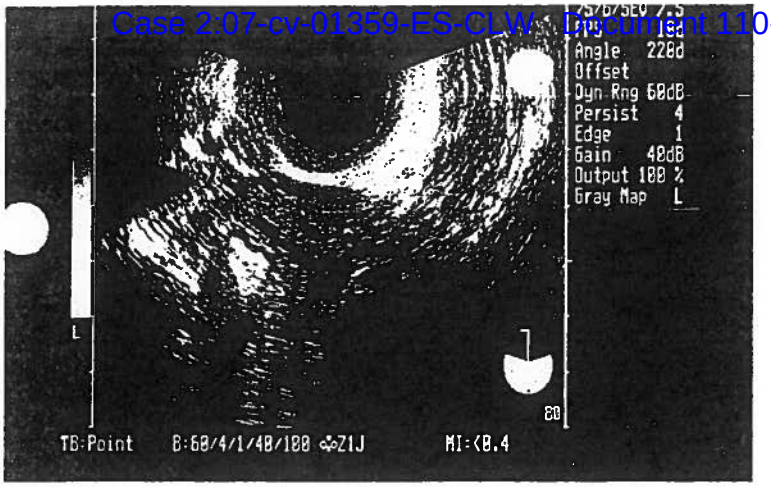
The pap smear is a screening test and is associated with an irreducible false negative rate. If clinically indicated, further investigation is suggested. This specimen was prepared using the Cytyc ThinPrep System.

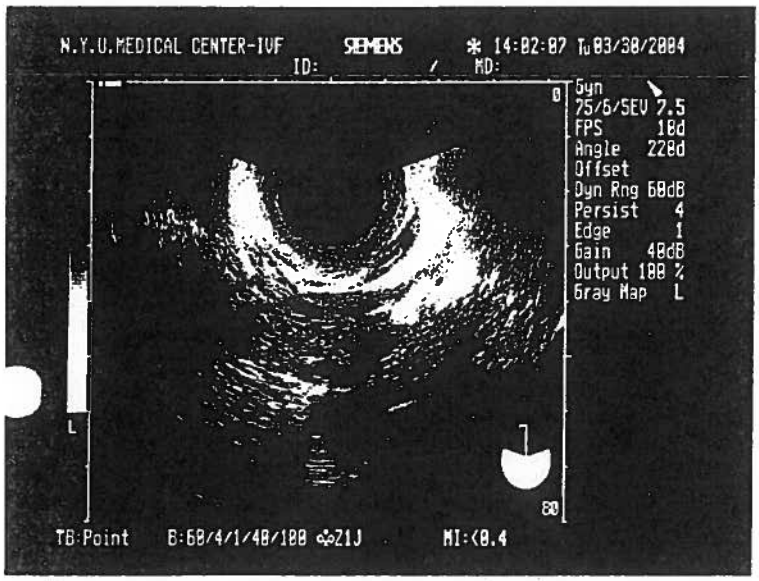
Grace Wong

Grace Wong, CT

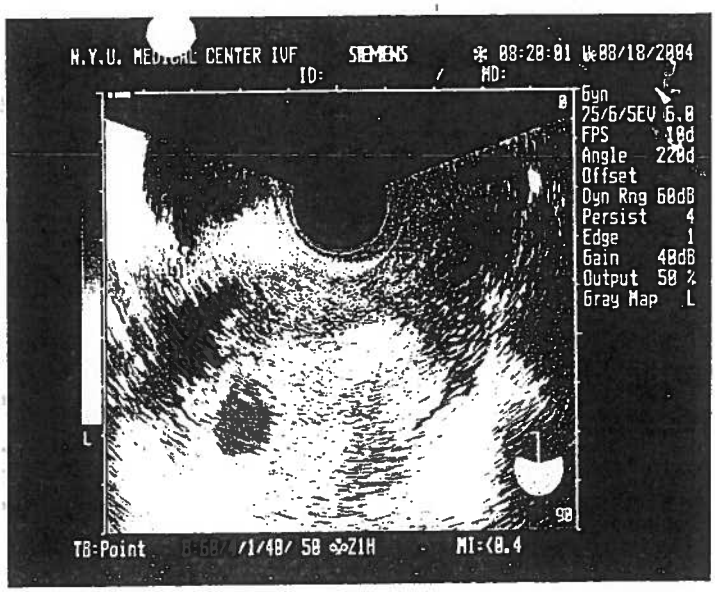
216 Congers Road
New City, NY 10956
(845) 638-4800

Tests Performed by DIANON Systems at 216 Congers Road New City NY 845-638-4800

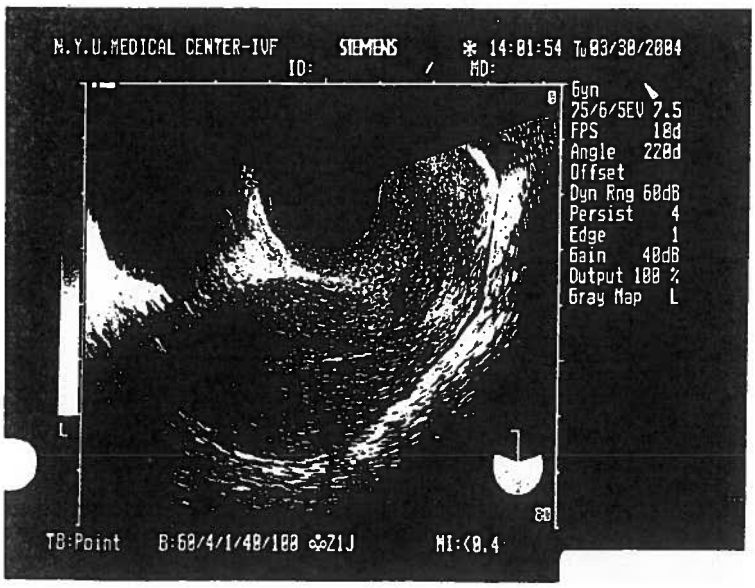


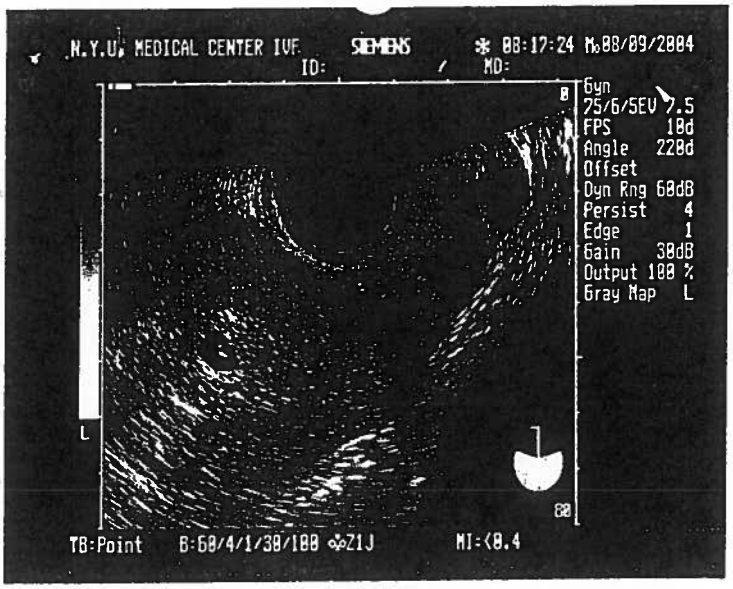


Chaya Grossbaum

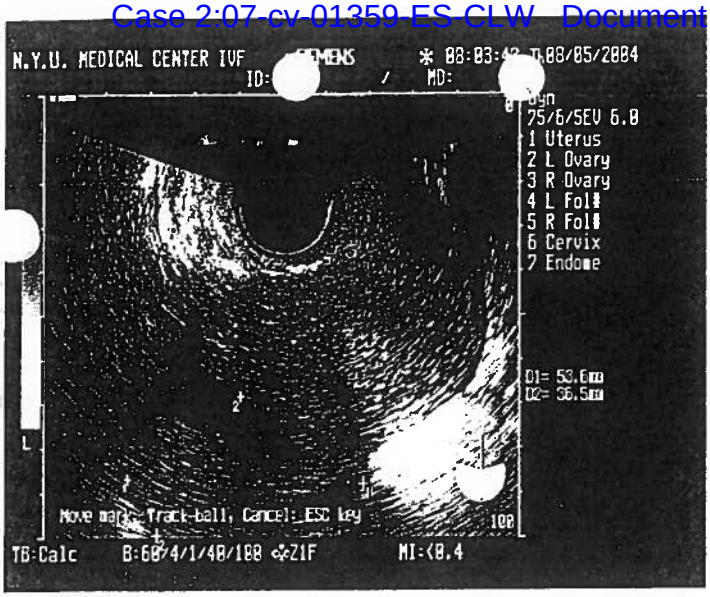


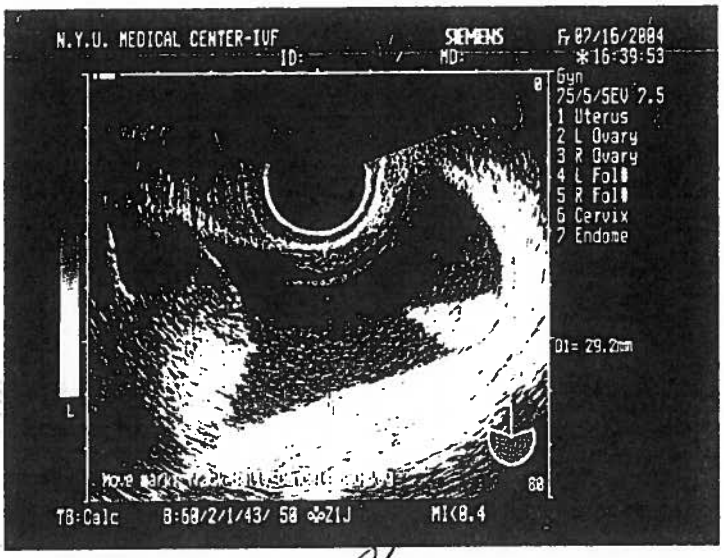
Chaya Grossbaum Morgenstern



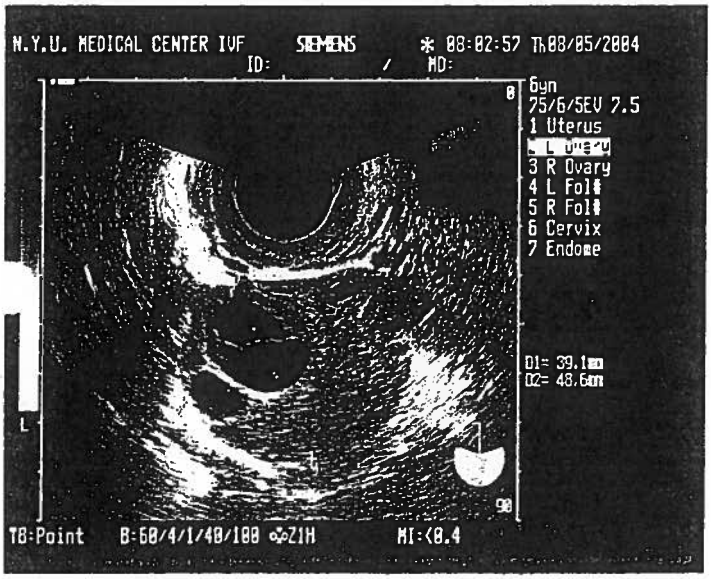


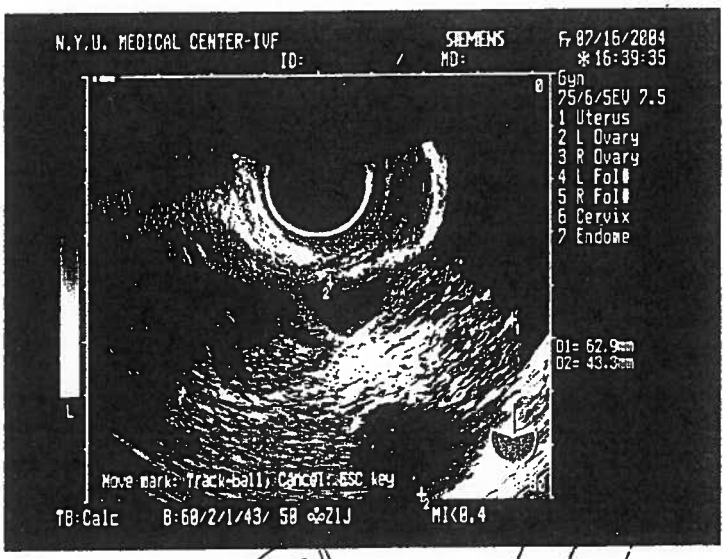
Chaya Grossbaum





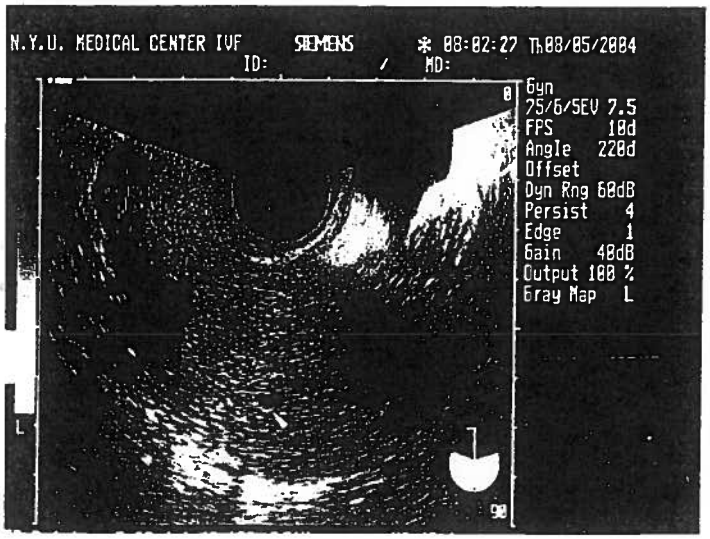
Grossbaum Chaya



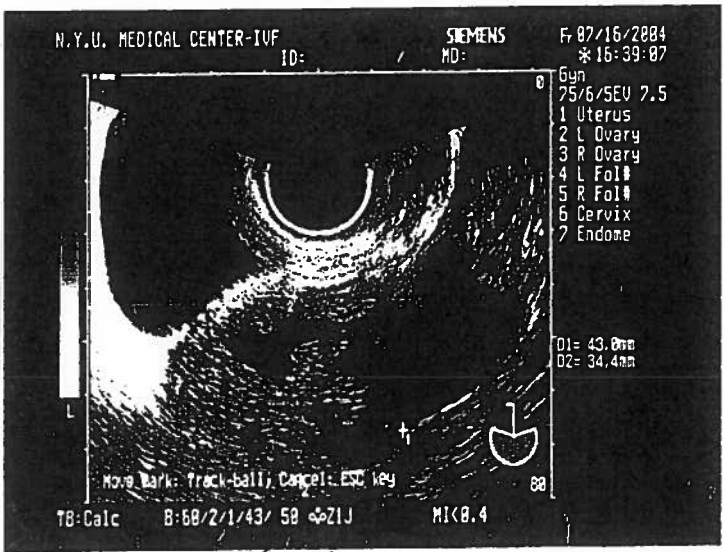


Chaya Grossbaum - Morgenstein

7/16/04



CG116



ient's Name: G ıum, Chaya . Phone (H): (W): DOB: (Age: 27 Primary MD: Licciardi

ernate Id: Med/Surg History: no Allergies: No Known Allergies

tner's Name: MENACHEM GROSSBAUM Partner's DOB:

cle:	Procedure:	Start Date:
	IVF	03/31/2004

of Previous Attempts: 0

ere: 0 Elsewhere: 0

eries: 0 ICSI: Not Entered

mbryology Summary:

ycle: 1 IVF (03/31/2004); Ret: 33. Trans: 2.

G: NE EL/AB: NE SP/AB: NE ECT NE

P: NE Primary: PGD Not Entered

Sounding: 0

○ Easy ○ Diff

Age at start: 24

Protocol:

FSH: Follistim IU: 225

HMG: IU:

LUP: Lupron Misc:

Default from Most Recent Plan Protocol: OK

☐ Blast ☐ EB ☐ TB ☐ Co-culture

Comments: 06/04/2004 12:58:00 PM cbr
PGD for CF

Ad

☐ Satellite ☐ DER ☐ Hormone Replacement Embryos to Transfer: 0

CBC Date CB ☐ Frozen Backup ☐ Testicular BX

SA Date: Count: ☐ MVP ☐ Asthma ☐ Abx at Ret.

Motility: Morph:

ate:	06/04/2004	06/11/2004	06/25/2004	07/06/2004	07/07/2004	07/08/2004	07/09/2004	07/10/2004	07/11/2004	07/12/2004	07/13/2004	07/14/2004	07/15/2004	07/16/2004	07/17/2004
ycle Day:	21		3	3	4	5	6	7	8	9	10	11	12	13	14
all Status:	Left Messag	In Person	In Person	In Person			In Person		In Person	In Person	Not Called				
urse Called:	iw			jw			sp		akw	sp	sp				
SH AM:															
PM:				225	225	225	150	150	150						
MG AM:															
PM:															
lomid:															
upron:		0.2cc	0.2cc	0.1cc	0.1cc	0.1cc	0.1cc	0.1cc	0.1cc						
strogen:			86	67			708		1644	2667	4414				
SH:															
H:															
4:	0.8	13													
CG:											112				
RL:															
SH:															
Revised by:															
Date:															
ndometrium:			5 Solid						9 Ring	11.5 Ring					
ltrasound R:			PCO	PCO					16 15 15 13.5 ++	18 17 16.5 16.5 +					
L:			PCO	PCO					16 14 15 ++	18 16 15.5 15.5 +					
omments:			stay on 2					cant come in		hcg 10000 #1					

New York University
School of Medicine
660 First Avenue, 5th Floor New York, NY 10016

Embryo Tracking

Patient Name: Grossbaum, Chaya **Phone(H):** **(W):** **SSN:** **DOB:**

Partner Name: MENACHEM GROSSBAUM **Part.DOB:** **MD:** Licciardi **Alternate Id:**

Med/Surg History: no **Allergies:** No Known Allergies

Cycle Number: 9188

Oocyte	Day 0 Time: /2004 10:35:00 AM				Day 1 Time: 07/15/2004 8:20:00 AM Embryo					Day 2 Time: 07/16/2004 11:33:00 AM Embryo						Day 3 Time: 07/17/2004 9:04:00 AM Embryo							
1	3	MII	I	C	0				C	2		1	0pn		C	4	5	2	0pn			D
2	3	MII	I	C	2				C	4	10	2			C	8	10	2		☑		C
3	3	MII	I	C	2				C	2		1.5			C	3	5	2	4-c	☑		C
4	3	MII	I	C	2		faint		C	2	5	1.5			C	4		2		☑		C
5	3	MII	I	C	0		deg		D													
6	3	MII	I	C	0		deg		D													
7	3	MII	I	C	2				C	5	10	2			C	7	5	2		☑		C
8	3	MII	I	C	2				C	4	15	3	asym		C	8	10	2		☑		C
9	3	MII	I	C	2				C	2	5	1.5			C	4	10	2		☑		C
10	3	MII	I	C	2				C	4		1.5			C	4		2	no growth	☑		C
11	3	MII	I	C	0				C	2		1.5	0pn		C	4	10	2	0PN			
12	3	MII	I	C	0				C	1					C	1						
13	3	MII	I	C	2				C	2		1.5			C	4		2		☑		C
14	3	MII	I	C	2				C	4	15	2.5			C	7	15	2.5		☑		C
15	3	MII	I	C	2				C	2	5	1.5			C	4	10	2		☑		C
16	3	MI		R																		

Grades:

1 - Symmetric blastomeres, no fragmentations or granularity
2 - Slight asymmetry, fragmentations or granularity
3 - Moderate asymmetry, fragmentations or granularity
4 - Severe asymmetry, fragmentations or granularity

Patient Name:	Grossbaum, Chaya	**Phone(H):**	**(W):**	**SSN:**	**DOB:**
Partner Name:	MENACHEM GROSSBAUM	**Part.DOB:**	**MD:** Licciardi	**Alternate Id:**	
Med/Surg History:	no		**Allergies:** No Known Allergies		

Cycle Number: 9188

Oocyte	Day 0 Time: /2004 10:35:00 AM			Day 1 Time: 07/15/2004 8:20:00 AM Embryo	Day 2 Time: 07/16/2004 11:33:00 AM Embryo	Day 3 Time: 07/17/2004 9:04:00 AM Embryo
17	3	MI	R			
18	3	MI	R			
19	3	GV	R			
20	3	GV	R			
21	3	GV	R			
22	3	GV	R			
23	3	GV	R			
24	3	GV	R			
25	3	GV	R			
26	3	GV	R			
27	3	GV	R			
28	3	GV	R			
29	2	GV	R			
30	2	GV	R			
31	2	GV	R			
32	2	FZP	D			
33	2	FZP	D			

Grades:

1 - Symmetric blastomeres, no fragmentations or granularity
2 - Slight asymmetry, fragmentations or granularity
3 - Moderate asymmetry, fragmentations or granularity
4 - Severe asymmetry, fragmentations or granularity

New York University
School of Medicine
660 First Avenue, 5th Floor New York, NY 10016

Embryo Tracking for Blastocyst Culture

Patient Name: Grossbaum, Chaya **Phone(H):** (W): **SSN:** **DOB:** A

Partner Name: MENACHEM GROSSBAUM **Part.DOB:** **MD:** Licciardi **Alternate Id:**

Med/Surg History: no **Allergies:** No Known Allergies

Cycle Number: 9188

	Day 4			Day 5 First (Time: 9:58:00 AM)				Day 5 Second				Day 6 (Time: 10:26:00 AM)			
		Embryo			Grade	Embryo			Grade	Embryo			Grade	Embryo	
2				morula		nice cav forming	D								
3				cleavage		6c	D								
4				cleavage		3c		cleavage		carrier	C	cleavage			D
7				morula				blast	1	carrier	T				
8				blast	2Cc	st to hatch		blast	3Bb	carrier	T				
9				cleavage		st to compact	D								
10				early morula				early morula		carrier	C	cleavage			D
13				morula				morula		carrier	C	blast	1		D
14				early morula			D								
15				morula				morula		carrier	C	morula			D

Grades:

1 - Early blastocyst; the blastocoel being less than half the volume of the embryo
2 - Blastocyst; the blastocoel being greater than half the volume of the embryo
3 - Full blastocyst; the blastocoel completely fills the embryo
4 - Expanded blastocyst; the blastocoel volume is now larger than that of the early embryo and the zona is thinning
5 - Hatching blastocyst; the trophectoderm has started to heniate through the zona
6 - Hatching blastocyst; the blastocyst has completely escaped from the zona

A - Tightly packed, many cells
B - Loosely grouped, several cells
C - Very few cells
D - Indistinct
a - Many cells forming a cohesive epithelium
b - Few cells forming a loose epithelium
c - Very few cells
d - Very poor

tient's Name: C baum, Chaya . | Phone (H): | (W): | SSN: | DOB | Age: 27

rtner's Nam: MENACHEM GROSSB | Partner's DOB | Primary MD: Licciardi | Affiliate MD: Not Entered | Alternate Id

d/Surg History: no | Allergies: No Known Allergies

cle: | Procedure: IVF | Start Date: 07/21/2004 | ☐ Satellite ☐ DER Blood Type: | ☐ Blast ☐ EB ☐ TB ☐ Co-culture

Comments: Not Entered | Add

Date:	07/21/2004	07/28/2004	07/30/2004	08/01/2004	08/03/2004	08/05/2004	08/09/2004	
Cycle Day:	21	28	30	32	34	36	40	
Call Status	Not Called	In Person	In Person	In Person	In Person	In Person	In Person	
Nurse Called:	sp	lgm	iw			lgm		
Estrace:								
Progesterone:								
Estrogen:		1222			1665			
FSH:								
LH:								
P4:	91.3	62			> 100			
HCG:		47	66	174	381	897	3942	
PRL:								
TSH:								
Revised by:								
Date:								
Comments:								

Obstetrician
Name:
Address:
Phone:

Retrieval Date:
Transfer Date:

Embryos
Transferred:
Frozen this cycle:

Trial CatheterType:
Transfer Catheter Type:
MD at Transfer: Not Entered

OB Ultrasound Record

Cycle Day	Date	Gestational Sac	Yolk Sac	Fetal Pole	Fetal Heart	Adnexa	Comments	MD Sign
	08/05/2004	tiny sac						
	08/09/2004	6	2.9	-	-			Licciardi
	08/18/2004	16	3.5	6.7	+			Licciardi

Find | Print | Save | Close

B"H

Wednesday, November 17, 2004

Dear Aurea,
I was a patient of Dr. Licciardi's and I need my medical records sent to the:
Midwives of Denville
550 West Main Street – Suite #5
Boonton NJ, 07005

fax 973-335-7753

If you have any questions or problems, their number is 973-334-6623 and my number is [redacted]. If you can, please call me to confirm that the records were sent.

Thank you,

Chaya Rochel Grossbaum-Morgenstern

11-19-04
mailed to pt
faxed to doctor
AMR

B"H

Wednesday, November 17, 2004

Dear Aurea,
I was a patient of Dr. Licciardi's and I need my medical records sent to the:
Midwives of Denville
550 West Main Street – Suite #5
Boonton NJ, 07005

If you have any questions or problems, their number is 973-334-6623 and my number is [redacted]. If you can, please call me to confirm that the records were sent.

Thank you,

Chaya Rochel Grossbaum-Morgenstern

New York Univ ersity
School of Medicine
660 First Avenue, 5th Floor New York, NY 10016

Retrieved from Archives 10/17/2008 AND ADDED TO PATIENT CHART

IVF Summary

Patient Name: GROSSBAUM, CHAYA Med/Surg History: no SSN: DOB:

Partner Name: MENACHEM GROSSBAUM Phone(H): (W): Allergies: No Known Aller MD: Licciardi Age: 24

IVF Cycle#: 9188 ☑ ICSI ☐ Blast ☐ AH ☑ EB ☐ GLC Incubator Number 9 Review: Date:

Consent

IVF-AH	☑ 4/19/2004	Donor Sperm	☐
IVF-ICSI	☑ 4/19/2004	Donor Egg	☐
CRYO	☑ 4/19/2004	Research IRB	☑

Comment: PGD ok 6/4/04. NY State PGD ok 6/4/04. Decline Research.

Procedure	Initials		Date/Time
Retrieval	cle	cmc	7/14/2004 10:35:00 AM
Sperm Preparation	aw	em	7/14/2004 10:25:00 AM
Insemination/ICSI	jl	em	7/14/2004 4:58:00 PM
Fertilization	cmc		7/15/2004 8:20:00 AM
Day 2 Check	em		7/16/2004 11:33:00 AM
Day 3 Check	pal		7/17/2004 9:04:00 AM
Assisted Hatching	jag	aa	7/17/2004 9:58:00 AM
Day 5 Check:	aa		7/19/2004 9:58:00 AM
Day 6 Check:	aa		7/20/2004 10:26:00 AM
Embryo Transfer	aa	jl	7/19/2004 3:27:00 PM
Cryopreservation Day			
Cryopreservation Day			
Cryopreservation Day			

Culture Data

	Media:	Lot:
d0:	HTF+ plasm 6%	9012540657
d1:	Quinns Cleav	4154a
d3:	Quinns Blast	4154c

Oocyte Recipient ☐
Sperm Donor ☐

SPERM DATA

Type: Fresh ☐ Frozen ☐ Donor
Preparation: Isolate
Supplement: Chymotrypsin
Sperm/Drop:

	Sample	PP
Accession#:	40738	
Vol (cc)	5.5	3
Conc (10 6	38	23
Motile (%)	42	92
Normal (%)		
Progression	2	3.5

Sperm Comments:

Prev Attempts: Here = 0; Elsewhere = 0

Diagnosis: Primary = PGD; Secondary = Not Entered

EMBRYO TRANSFER

Embryologist: aa Tenaculum ☐
MD: fl Pain ☐
Catheter: Wallace
Difficulty: Easy
Blood:
Embryos Retained ☐
Comments:

EMBRYOLOGY SUMMARY

# Eggs Retrieved:	33
# Eggs Inseminated:	0
# Eggs ICSI:	15
# Eggs Fertilized (1pn):	0
# Eggs Fertilized (2pn):	10
# Eggs Fertilized (3pn):	0
# Embryos Assisted Hatching:	10
# Embryos Transferred:	2
# Embryos Frozen Day	0
# Embryos Frozen Day	0
# Embryos Frozen Day	0
# Eggs Late Fert:	
Embryo Quality:	good
# of Day 1 ICSI eggs:	0

Egg/Embryo Comments: PGD for CF.15/33 mature-10 fert w/ICSI
2 et, both blasts, both carriers

genesis
genetics institute
The Trowbridge Historial House
1380 East Jefferson Avenue
Detroit, MI 40207
tel/fax: 313-544-4006
www.genesisgenetics.com

Genesis Genetics Institute Fax

313-544-4006 (return e-fax & phone)

To: Alexis or IVF lab

Fax: 212-263-[redacted]0059 **Date:** 7/19/04

Phone: 212-263-7807 **Pages:** (Incl Cover): 2

RE: PGD

☒ Urgent ☐ For your review/records ☐ Reply ASAP

Results of CF case.

CG125

ent's Name: GRO ...UM, CHAYA | Med/Surg History: | DOB | Age: 23 | Primary MD: Licciardi

ner's Name: MENACHEM GRO ...BAUM | Phone (H): | (W): | SSN: | Allergies: | Aff. MD: Not Entered

#1

DOB: 1/1/56

cle:	Procedure:	Start Date:
	IVF	3/31/2004

f Previous Attempts: 0

re: 0 Elsewhere: 0

es: 0 ICSI: Not Entered

G: NE EL/AB: NE SP/AB: NE ECT NE

P: NE Primary: Not Entered Not Entered

Protocol: FSH: Follistim Amps: 3

HMG: Amps:

LUP: Lupron Misc:

Default from Most Recent Plan Protocol: OK

☐ Blast ☐ EB ☐ TB ☐ Co-culture

Sounding: 0 ○ Easy ○ Diff

Comments: Not Entered

Ad

CF RGD ō Dr. Hughes SA 4/04
consents OK (10) 25ND 6/mL
62% mobile
290 normal morph

☐ Satellite ☐ DER ☐ Hormone Replacement Embryos to Transfer: 0

CBC Date: 5/25/04 Requision #:

CBC Result: Cycle Length:

#1 Cell 973 216 8640

	6/4/04	6/11/04	[illegible]	7/6	7/7	7/8	7/9/04	7/10/04	7/11/04	7/12				
ay:	20	11 5/8		11 5/8	9	5	6	7	8	9			IVF Consents OK 4/04	
ll Status:	left ovary													
rse Called:	JW								AK					
H AM:							7/8						KSI OK	RH OK
PM:				225	225	225	150	150	150	HCG			No Donor	No Results
MG AM:														
PM:													CRYO CONSENTS OK 4/04	
omid:													RGD Consents OK 6/04	
pron:		0.2	.2	.1	.1	.1	.1	.1	0.1					
trogen:			86	67			708		1614	2667.0			NY State PGD OK 6/04	
H:														
l:	0.8	13												
:														
CG:														
RL:														
s														
Revised by:														
Date:														
idometrium:			7.5						7.9R	11.5R				
trasound R:			PCO	PCO					13.5 16 16 15	17 18 16.5 10.5				
L:			PCO	PCO					10 15 14	18 16 15.5 15.5				
omments:				ok			Can't come in Sat							

Find | drology | IVF Sum/FET | HCG | [illegible] | Save | Close

CG126

Key# 00000228
Acct# 00022484
grossbaum, chaya

pd

Partner's Name: MENACHEM GROSSBAUM Phone (H): (W): SSN: Allergies: Aff. MD: Not Entered

Cycle:	Procedure:	Start Date:
1	IVF	3/31/2004

# of Previous Attempts: 0
Here: 0 Elsewhere: 0
Series: 0 ICSI: Not Entered

G: NE EL/AB: NE SP/AB: NE ECT NE
P: NE Primary: Not Entered Not Entered

Protocol: FSH: Follistim Amps: 3
HMG: Amps:
LUP: Lupron Misc:
Default from Most Recent Plan Protocol: OK
☐ Blast ☐ EB ☐ TB ☐ Co-culture

Sounding: 0 ○ Easy ○ Diff

Comments: Not Entered
Ad
CF Rec'd & Dr Hughes consents OK (10)
SA 4/04
25 M 10^6/mL
629 motile
290 normal morph

☐ Satellite ☐ DER ☐ Hormone Replacement Embryos to Transfer: 0

CBC Date: 6/15/04 Requision #:
CBC Result: Cycle Length:

#1 CELL 973 216 8640

Day:	6/10/04	6/11/04	7/6	7/6	7/8	7/8	7/9/04	7/10/04	7/11/04	7/12	7/13/04				
Day:	20		11	11	5	5	6	7	8		10		IVF Consents OK 4/04		
Call status:	left vm								AK						
Nurse Called:	(IW)	(IW)	(IW)				IW								
FSH AM:							58						KSI OK	AK OK	
PM:			225	225	225	225	150	150	150				No Demand	No Response	
HMG AM:															
PM:													CRYO CONSENT OK 4/04		
Clomid:															
Lupron:		0.20	.2	.1	.1	.1	.1	.1	0.1				RGT CONSENTS OK 6/04		
Estrogen:			86	67			708		1604	2667.0	1407 4414		NY STATE	PGD	OK 6/04
FSH:															
LH:															
P4:	0.8	13													
HCG:											112				
PRL:															
TT:															
Revised by:															
Date:															
Endometrium:			7.55						9R	11.5R					
Ultrasound R:			PLO	PLO					13.5 15 15	17 18 16.5 16					
L:			PLO	PLO					16 15 14	18 16 15.5					
Comments:				ok				Can't come in sent							

Find | Urology | IVF Sum/FET | HCG | Save | Close

CG127

NYU PROGRAM FOR IVF
660 First Avenue, 5th Floor
New York, NY 10016

ICSI Summary Sheet

Name: GROSSBAUM, CHAYA
Partner: MENACHEM GROSSBAUM
SSN:
DOB:

IVF Cycle # : 9189

Patient Age: 23 y/o

Retrieval Date: 7/14/04

Comments:

Sperm Origin

Fresh ☑ Frozen ☐ Testicular ☐ Epididymal ☐ EEP ☐

Oocyte #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Embryologist	JL	—	—	—	—	—	—	—	—	—	—	—	—	—	↘			
Oocyte Morphology																		
Sperm Morphology																		
PB Position	12	12	12	6	12	6	12	12	12	12	6	12	12	12	12			
Area Of Organelle Concentration		11-12	12	Center	left	Center	left		Center	6			12	8	Center			
Immediate Membrane Breakage					✓	✓				✓					✓			
Stirring																		
Touched The Other Side																		
# Stabs																		

Oocyte Recipient ☐ EB ☐

JL/Em

CG128

PROGRAM FOR IN-VITRO FERTILIZATION
REPRODUCTIVE SURGERY AND INFERTILITY

IVF / Andrology Laboratory
660 First Avenue, 5th Floor
New York, NY 10016

Tel: (212) 263-8990
Fax: (212) 263-0059

IVF SEMEN COLLECTION RECORD

Physician: Licciardi

Accession ID: 040738

Patient Name (Male Partner): Menachem Mendel Grossbaum Date of birth: _

(Female Partner): Chaya R Grossbaum

How was this sample obtained:

Masturbation	____
Intercourse with a condom	X
Intercourse with withdrawal	____

How many days did you abstain before ejaculation? 2
The date 7/14/04 and time 7:45 am AM / PM this sample was collected.

Were there any collection or transport problems (e.g., incomplete specimen, exposure to temperature extremes, or spilled sample)? YES or NO
If yes, please describe: _____

Are you taking any medication? YES or NO. If yes, please indicate the name: _____

Have you had any illness in the past month? YES or NO
If yes, please specify: _____

STATEMENT OF VERIFICATION: I Menachem Grossbaum, verify that this sample was produced by me / my partner. The sample was given to a laboratory technologist whose signature appears below.

_____ 7/14/04
Signature of Patient Date

The staff of NYU-PIVF is authorized to release the results of all testing performed on this semen specimen to my partner/spouse Chaya R Grossbaum for a period of one (1) year from the date of this authorization.
Signature _____ 7/14/04

OFFICE USE ONLY:

Type of specimen container:

Sterile 4.5 oz Specimen Container	X
Male Pak Sterile Condom	____
Other Container	____

Specimen collected at: **Home or outside NYUMC-IVF facility** ✓ **NYUMC-IVF facility** ____
Time Specimen was received: 9:10 **AM / PM**

EM 7/14/04
Laboratory Technologist Date

NYU Program for IVF
660 1st Ave. 5th Fl.
New York, NY 10016

Date: 7/14/04
Time: 9:30
Embryologist: CE / EM

SEMEN ANALYSIS WORKSHEET

Patient's Name: GROSSBAUM, CHAYA Date of birth
Partner: MENACHEM GROSSBAUM
Partner's Name: SSN: Date of birth
DOB:

Frozen Sperm

Donor #: Vial #:
Cryo Bank: #vials used: #vials remaining:

Semen Analysis: Accession # 040738

Volume: 5.5 ml (Normal > 2.0ml)
Count: 38 X 10^6/ml (Normal > 20 X 10^6/ml)
% Motility: 42 % (Normal > 40%)
Progression: 2 (Range: 1-4, Normal > 2)
Viscosity: Normal Agglutination: NO
Comments:

Post Processing/Final Sperm Recovery Embryologist: CE

Time Analyzed: 10:25

Sperm Preparation Technique:

supplements:

Swim-up from seminal fluid
Swim-up from sperm pellet
Isolate Gradient ✓
Spin down wash @1800G

Chymotrypsin: ✓
Pentoxy/Deoxyadenosine:

Volume: 3.0 ml
Sperm Count: 23 X 10^6/ml
% Motility: 92 %
Progression: 3+ Total Motile Sperm Recovered: 63.48
Comments:

2/04 AA

Dear Dr. Hughes:

Here is the information you that you requested:

1) A total 10 embryos were biopsied today.

2) There are 20 tubes in rack.

10 out of 20 are containing single cell, they are labeled as

2, 3, 4, 7, 8, 9, 10, 13, 14, 15

10 out of 20 are control samples containing medium which the single cells were washed in. They are labeled as

2B, 3B, 4B, 7B, 8B, 9B, 10B, 13B, 14B, 15B

There are no control samples for

If you have any question, please feel free to contact us.

Best regards,

Alexis Adler
Caroline McCaffrey
Embryology Laboratory
212-263-7807

NYU PROG. A FOR IVF
660 First Avenue, 5th Floor
New York, NY 10016

EMBRYO TRACKING RECORD

NAME: GROSSBAUM, CHAYA
Partner: MENACHEM GROSSBAUM
SSN:
DOB:

AGE: 23
INCUBATOR # : 9
RETRIEVAL DATE: 7/14/04
IVF CYCLE # : 9188

DAY 0 Time:				DAY 1 Time:			DAY 2 Time:				DAY 3 Time:					
Oocyte#	Grade	Maturity	ICSI	#PN	Maturity	Embryo Description	# Cells	% Frag	Grade	Embryo Description	# Cells	% Frag	Grade	Embryo Description	AH	DISPOSITON
21	3	GV														R
22	3	GV														R
23	3	GV														R
24	3	GV														R
25	3	GV														R
26	3	GV														R
27	3	GV														R
28	3	GV														R
29	2	GV														R
30	2	GV														R
31	2	GV														R
32	2	atretic														
33	2	atretic														
14																
15																
16																
17																
18																
19																
20																

Oocyte Grade: 1 = Immature
2 = Semi-mature
3 = Mature
4 = Post mature

Oocyte Maturity: GV = Germinal Vesicle
MI = Metaphase I
MII = Metaphase II (PB)

Embryo Grade: 1 = Symmetric blastomeres, no fragmentations or granularity
2 = Slight asymmetry, fragmentation or granularity
3 = Moderate asymmetry, fragmentation or granularity
4 = Severe asymmetry, fragmentation or granularity

NYU PROG. A FOR IVF
660 First Avenue, 5th Floor
New York, NY 10016

CLE/CRM

EMBRYO TRACKING RECORD

NAME: GROSSBAUM, CHAYA
Partner: MENACHEM GROSSBAUM
SSN:
DOB

AGE: 33
INCUBATOR #: 9
RETRIEVAL DATE: 7/14/04
IVF CYCLE #: 9188

DAY 0 Time:				DAY 1 Time: 8:15			DAY 2 Time:				DAY 3 Time: 9:00					
Oocyte#	Grade	Maturity	ICSI	#PN	Maturity	Embryo Description	# Cells	% Frag	Grade	Embryo Description	# Cells	% Frag	Grade	Embryo Description	AH + Biopsy	DISPOSITION
1	W	M2	✓	0			2		1	0 PN	4c	5	2	0PN		D
2	W	M2	✓	2			4	10	2		8c	10	2		✓	V
3	W	M2	✓	2		fourb	2		1.5		3c	5	2	→ 4c	✓	V
4	W	M2	✓	2			2	5	1.5		4c	-	2		✓	V
5	W	M2	✓	0		deg										D
6	W	M2	✓	0		deg										D
7	W	M2	✓	2			4	10	2		7c	5	2		✓	V
8	W	M2	✓	2			4	15	3	asym.	8c	10	2		✓	V
9	W	M2	✓	2			2	5	1.5		4c	10	2		✓	V
10	W	M2	✓	2			4		1.5		4c		2	No growth	✓	V
11	W	M2	✓	0			2		1.5	0 PN	4c	10	2	0PN		D
12	W	M2	✓	0			1c				1c					
13	W	M2	✓	2			2		1.5		4c		2		✓	V
14	W	M2	✓	2			4	5	2.5		7c	15	2.5		✓	V
15	W	M2	✓	2			2	5	1.5		4c	10	2		✓	V
16	W	M1														R
17	W	M1														R
18	W	M1														R
19	W	GV														R
20	W	GV														R

Oocyte Grade: 1 = Immature; 2 = Semi-mature; 3 = Mature; 4 = Post mature

Oocyte Maturity: GV = Germinal Vesicle; MI = Metaphase I; MII = Metaphase II (PB)

Embryo Grade: 1 = Symmetric blastomeres, no fragmentations or granularity; 2 = Slight asymmetry, fragmentation or granularity; 3 = Moderate asymmetry, fragmentation or granularity; 4 = Severe asymmetry, fragmentation or granularity

EMBRYO TRACKING RECORD FOR BLASTOCYST CULTURE

Name: GROSSBAUM, CHAYA
Partner: MENACHEM GROSSBAUM
SSN:
DOB:

IVF Cycle #: 9188
Patient Age: 23
Media: Q Incubator # : 9

Retrieval Date: 9788 7/14/09
Transfer Date:
Comments: PGD-CF

Embryo #	Drop #	Day 5 Time: 915 Embryo Stage	Grade	Embryo Description	Day 5 Time: Embryo Stage	Grade	Embryo Description	Disposition	Day 6 Time: Embryo Stage	Grade	Embryo Description	Disposition
2	4	mor/bl		nice - cav forming								
3		4c		6c								
4	2	4c		3c	4c				4c			D
7		morula			1			T				
8	3	2-3	cc	8-to hatch	3	BB	8-to hatch	T				
9		8c		8-to compact								
10	4	L mor/bl			L mor/bl				4c			D
13		mor/bl			morula		w/cav forming		1			D
14	5	L mor/bl										
15		mor/bl			morula				mor/bl			D
	6											
	7											
	8											

Scoring System (Grade) for Human Blastocysts = Degree of Expansion and Hatching Status, ICM Grading and Trophectoderm Grading (ex: 4AA)

Degree of Expansion and Hatching Status
1 = Early blastocyst; the blastocoel being less than half the volume of the embryo
2 = Blastocyst; the blastocoel being grater than half of the volume of the embryo
3 = Full blastocyst; the blastocoel completely fills the embryo
4 = Expanded blastocyst; the blastocoel volume is now larger than that of the early embryo and the zona thinning
5 = Hatching blastocyst; the trophectoderm has started to heniate through the zona
6 = Hatched blastocyst; the blastocyst has completely escaped from the zona

ICM Grading
A = Tightly packed, many cells
B = Loosely grouped, several cells
C = Very few cells
D = ICM indistinct

Trophectoderm Grading
A = Many cells forming a cohesive epithelium
B = Few cells forming a loose epithelium
C = Very few cells
D = Very poor

CG134

Blastomere Biopsy Cover Sheet

Please use these data sheets unless you are directly connected to our Server for confidential patie data exchange

Clinical IVF Center (Your Center's Name): NYU

Patient Last Name: Gross Baum

Patient First Name: Chaya

Person performing the Biopsies: Grifo / Aiden

PGD Attempt Number for this Patient: 1

Biopsy (Today's) Date: 7/7/04

Time you started biopsies (local time): 1000

Time you finished all biopsies: 1100

Our IVF center evaluates embryo quality with the following nomenclature (used on the attached forms)
(Please check one)

- ☐ Rating 1 through 5 (where 5 is best)
- ☒ Rating 1 through 5 (where 1 is best)
- ☐ Rating 1 through 3 (where 3 is best)
- ☐ Rating 1 thourgh 3 (where 1 is best)
- ☐ Other: _____

Markin Express Courier Job Number: _____

Expected Arrival Time: 1

After completing the attached form(s), please make a xerox copy for your records, & one for the sample shipping box. Then PLEASE fax this one to us at 313-577-6200 so that we can prepare for the diagnostics before the blastomeres arrive. Thank you!

embryo biopsy

Embryo Biopsy						
Patient				Grossbaum, Chaya	CF	
Date			7/17/2004			
Diagnosis						
embryo#	# cells		biopsy	#blastomeres	intact	pcr
1						
2	8		6	1	4	
3	4		-	1	4	
4	4		6	1	4	
5						
6						
7	7		6	1	4	
8	8		6	1	4	
9	4		6	1	4	
10	4		4	1	4	
11						
12						
13	4		6	1	4	
14	7		6	1	4	
15	4		6	1	4	

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Office of Institutional Board of Research Associate:
NYU School of Medicin
550 First Ave. Building #VET
10 West
NY, NY 10016
Phone: 212.263.4110
Fax: 212.263.4147

Principal Investigator: James A. Grifo, M.D., Ph.D.

INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

TITLE OF RESEARCH: RESEARCH STUDIES ON DISCARDED IVF TISSUES

A. PURPOSE OF THE STUDY:

In vitro fertilization (IVF) involves the fertilization of oocytes (eggs) by sperm in a culture dish in the laboratory. You are being asked to volunteer discarded materials (fluids, granulose cells, sperm, eggs, embryos) from your IVF cycle for use in a research study. This consent/authorization form includes information about this study.

In order to understand the biology how the human egg and sperm mature and how the early human embryo develops it is best to use human rather than animal tissues. Human tissues are also most appropriate when developing and assessing the safety of new procedures for the IVF laboratories, procedures used to culture, micromanipulate (handle an individual cell) and cryopreserve (freeze-thaw) eggs and embryos. During your IVF cycle, biologic specimens will often be discarded because they are either a procedural by-product (blood, follicle fluids, granulosa cells, excess sperm) or an abnormal result (immature oocytes, abnormally fertilized eggs, poor quality embryos unsuitable for transfer to the uterus or cryopreservation). The discarding of these fluids, cells and tissues differs from patient to patient. Although blood, follicle fluid, granulosa cells and sperm are routinely discarded from patients, we cannot predict whether a patient will or will not have immature eggs, abnormally fertilized eggs or poor quality embryos to discard. Thus, we are now seeking your consent to conduct these research studies should these discard materials be available.

The discarded materials will be used in many research studies. Discarded blood, follicle fluid, culture media and granulosa cell specimens are monitored to examine how ovarian hormones and growth factors influence egg development and whether they are secreted differently with different ovarian stimulation treatments. Discarded sperm, eggs and embryos are used to develop new laboratory micromanipulation techniques, freezing / thawing procedures and culture protocols. These cells and tissues are also used to assess cell levels of molecules that regulate how the egg matures, when the embryonic cells divide and whether they differentiate to develop into the fetus or the placenta. Finally, these discarded cells and tissues are used to develop and perform genetic testing procedures that determine if abnormalities in chromosome number or gene expression are associated with any of these new techniques or with a naturally occurring failure(s) of an embryo to develop normally.

 Subject's Initials: CRG-M mmG Date: 7/19/04 7/19/04

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B. SUBJECT PARTICIPATION:

We estimate that 750 subjects will enroll in this study at this site
(to date 400 subjects have been enrolled)

☐ Other (Patients at the Program for IVF, Reproductive Surgery and Infertility)

Your participation will involve 5-10 visits, which will take place over 2 months. These visits will take between 15 minutes and 3 hours. ***These are the visits for IVF. No additional visits are required for this study.***

C. DESCRIPTION OF THE RESEARCH:

You must also sign our program consent form (In Vitro Fertilization/Embryo Transfer ["IVF-ET"] Program Consent Form - Options for "Intracellular Sperm Injection" and "Assisted Hatching"). On this form you have the option to indicate which discarded specimens you wish released for research. For discarding cryopreserved (frozen) specimens you must also sign the "Release for Disposal of Cryopreserved Embryos."

Fluids and cells routinely obtained and discarded during the course of an IVF cycle will be used in research studies. Each specimen, especially each sperm preparation and each egg and embryo, is assigned an individual accession number by the embryology laboratory to ensure patient anonymity. Once in the research laboratory, the specimens are often assigned yet a second individual accession number. At the end of each study, each specimen is analyzed and then discarded by the laboratory; in many biochemical studies the cells or embryos are lysed (broken up into solution) prior to analysis. ***At no time are sperm, eggs or embryos transferred to another patient for their use.***

Discarded blood, ovarian granulosa cells and follicle fluids will be used to

1.Characterize and measure what hormones (testosterone, estradiol...) or growth factors are produced and secreted by granulosa cells, assay the levels of these hormones in blood, follicular fluid and discarded media from culture, develop genetic tests to assess the synthetic characteristics and capabilities of these cells and finally, determine whether this secretion(s) is related to an infertility diagnosis or is influenced by the ovarian stimulation treatment. These fluid specimens are often stored frozen until assay.

Discarded immature oocytes (eggs) will be used to

1. Develop staining procedures to monitor the cell mechanisms that regulate egg maturation.
2. Develop biochemical and genetic procedures to follow the cell mechanisms underlying the changes in chromosome number that occur during the final stages of egg maturation.
3. Assess cryopreservation, (freezing /thawing) procedures. Eggs will be stored frozen for a short interval (< 1 week) and then thawed and assessed for maturation, spindle formation and chromosome number.

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4. Test out new culture conditions (media and supplements) for in vitro maturation.
5. Exchange nuclei between immature fresh and frozen oocytes to show that they mature normally. Preliminary results suggest that this procedure may minimize aneuploidy (an abnormal number of chromosomes) that is often observed in the eggs of older women. In one study the nuclei will be transferred and matured in mouse eggs which have had their nuclei removed; other investigators have reported that this procedure can be used in an accurate diagnostic test to assess aneuploidy.

Discarded abnormally fertilized or poor quality embryos will be used to

1. Assess in vitro culture procedures which employ experimental media and culture conditions. Cell division of abnormal eggs or embryos is monitored for 3-5 days under different culture conditions as an initial step in testing; most embryos are then discarded but some are examined for gene or chromosome analysis.
2. Develop genetic procedures that will allow us to count chromosome number or to identify when genes are expressed to stimulate the production of their proteins in normal and abnormal eggs or in embryonic blastomeres (cells) at developmental stages up to blastocyst. The genes under investigation may be involved in embryo growth or differentiation and may be regulated by a variety of mechanisms. Inappropriate numbers or expression of certain genes may lead to birth defects or early pregnancy loss.
3. Determine the percentage of poor quality embryos that display defects in gene imprinting (control of the function of certain embryonic genes by parental factors). In mice such defects influence how an embryo develops and may cause embryo death prior to or following implantation in the uterus. Discarded granulosa and sperm cells will also be used in this study to indicate whether genes of interest are present on chromosomes of the male or female partner.

Discarded normally fertilized and good quality cryopreserved embryos will be used to

1. Develop analytical, genetic procedures to count chromosome number and to identify when genes are expressed to stimulate the production of their proteins in normal and abnormal oocytes or in embryonic blastomeres (cells) at developmental stages up to blastocyst. The genes under investigation may be involved in differentiation and growth of the embryo and may be regulated by a variety of mechanisms. Inappropriate numbers or expression of certain genes may lead to birth defects or early pregnancy loss.

D. COSTS/REIMBURSEMENTS:

You or, if appropriate, your insurance company are responsible for all costs associated with the in vitro fertilization (IVF) cycle which has been prescribed for you by your physician. There is no compensation for your participation in this study.

E. POTENTIAL RISKS AND DISCOMFORTS:

There are no potential risks or discomforts for you associated with this research since it is performed using fluids and cells routinely discarded during an in vitro fertilization cycle. Any potential risks and discomforts associated with the IVF procedures are discussed in our

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program's consent form (In Vitro Fertilization/Embryo Transfer ["IVF-ET"] Program Consent Form-Options for "Intracellular Sperm Injection" and "Assisted Hatching") which you must sign.

There are no risks to you for the genetic testing of your specimens since your specimens will be assigned anonymously to research studies. In addition tests that we are developing focus on describing what happens to chromosomes and genes in normally and abnormally developing embryos in all humans; these tests do not examine for mutations that cause disease.

F. POTENTIAL BENEFITS:

There are no immediate benefits to you for participating in this study. The proposed research will increase our understanding of the important factors regulating how eggs and sperm mature and function and how early embryos develop. Such an understanding may lead to the development of more effective hormone treatment protocols. The research may also lead to the development of new or improved technology in the embryology laboratory. Such procedures will expand the range of infertility disorders that can be treated with IVF and hopefully increase the chances that an IVF cycle will result in a pregnancy. Finally, these studies may also uncover genetic explanations for certain birth defects or early miscarriage losses.

G. ALTERNATIVES TO PARTICIPATING IN THE STUDY

Your decision to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study, this decision will not affect the care you receive during your IVF cycle and will not result in any loss of benefits to which you are otherwise entitled.

H. CONFIDENTIALITY:

Private information about you that identifies you may be used or shared for the purposes of this research project. This section of the consent/authorization form describes how your information will be used and shared in this research, and the ways in which NYU School of Medicine will safeguard your privacy and confidentiality.

If you agree to donate your discarded specimens for this research study, any test conducted on these discarded specimens by Dr. James Grifo and his research team will not be included in your medical record.

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study. Except when required by law, study information shared with persons and organizations outside of New York University School of Medicine (NYUSM) will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

When your study information will be disclosed outside of NYUSM as part of the research, the information that can identify you as listed above will be removed and your specimens and

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records will be assigned a unique code number. NYUSM will not disclose the code key, except as required by law.

Confidentiality of Your Medical Records

Your medical records will be kept in accordance with state and federal laws concerning the privacy and confidentiality of medical information. If your participation in this research is for treatment or diagnostic purposes, the facility in which you are treated may ask you to sign a separate informed consent document for specific procedures or treatment, and that informed consent form may be included in the medical record of that facility. The confidentiality of your medical record is also protected by federal privacy regulations, as described below.

Confidentiality of Your Study Information

Your study records include information that identifies your specimens and that is kept in research files. We will try to keep this information confidential, but we cannot guarantee it. If data from this study are to be published or presented, we will first take out the information that identifies you.

Retention of Your Study Information

The study results will be kept in a research record for at least six years or until after the study is completed, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at NYU. Any research information in your medical record will be kept indefinitely.

Your HIPAA Authorization

A new federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, in most cases we must seek your written permission to use or disclose identifiable health information about you that we use or create your "protected health information" in connection with research involving your treatment or medical records. This permission is called an Authorization.

If you sign this form you are giving your Authorization for the uses and sharing of your protected health information described below. You have a right to refuse to sign this form. If you do not sign the form you may not be in the research program, but refusing to sign will not affect your health care (or payment for your health care) outside the study.

This Authorization will not expire unless you withdraw it in writing. You have the right to withdraw your authorization at any time, except to the extent that NYU has already relied upon it or must continue to use your information to complete data analysis or to report data for this study. The procedure for revoking your authorization is described below in Section K.

By signing this form you authorize the use and disclosure of the following information for this research:

- The following information from your medical record: maternal age, body mass index, ovarian stimulation protocol, infertility diagnosis, intracytoplasmic sperm injection (ICSI – yes/no), clinical pregnancy history

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- Results of investigations in the Program for Infertility, Reproductive Surgery and Infertility – NYUSM on the specimens that are being collected with this study and future research on infertility.

By signing this form you authorize the following persons and organizations to receive your protected health information for purposes related to this research:

- The Program for In Vitro Fertilization, Reproductive Surgery and Infertility
- Any laboratories and other individuals and organizations that analyze your specimens in connection with this study in accordance with the study's protocol
- The United States research regulatory agencies and other foreign regulatory agencies
- The members and staff of the hospital's affiliated Institutional Review Board
- The members and staff of the hospital's affiliated Privacy Board
- Principal Investigator: James A. Grifo
- Study Coordinator
- Members of the Research Team
- Members of the NYU/NYUMC Clinical Trials Office/Office of Research and Sponsored Programs

If any of the companies or institutions listed above merges or is sold during the course of this research, your Authorization will cover uses and disclosures of your protected health information to the new company or institution that assumes responsibility for the research.

Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to redisclosure by the recipient.

I. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:

All forms of medical (or mental health) diagnosis and treatment – whether routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all precautions, you might develop medical complications from being in this study.

If you sustain any injury during the course of the research or experience any side effect to a study drug or procedure, please contact the Principal Investigator Dr. James A. Grifo at the following telephone number 212-263-8990. If such complications arise, the study doctor will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs. You do not give up any rights to seek payment for personal injury by signing this form.

J. VOLUNTARY PARTICIPATION AND AUTHORIZATION:

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Your decision as to whether or not to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled.

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.

Your decision as to whether to give your Authorization for the use and disclosure of your protected health information for this study is also completely voluntary; however, if you decline to give your Authorization or if you withdraw your Authorization you may not participate in the study.

K. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:

If you agree to allow your blood, follicular fluids, granulose cells, eggs, sperm and embryos to be kept for research, you are free to change your mind at any time. We ask that you contact Dr. James A. Grifo in writing and let him know you are withdrawing your permission for your blood, follicular fluids, granulose cells, eggs, sperm and embryos to be used for research. His mailing address is Program for IVF, 660 First Ave (5th Fl), New York, NY 10016. Any unused blood, follicular fluids, granulose cells, eggs, sperm and embryos will be discarded.

L. CONTACT PERSON(S):

For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Administrator, Institutional Board of Research Associates, Telephone No. 212-263-4110.

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study drug or procedure, please contact the Principal Investigator Dr. James A. Grifo at the following telephone number 212-263-8990.

AGREEMENT TO PARTICIPATE AND AUTHORIZATION FOR THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION:

Part of the consent process includes your Authorization to use Protected Health Information for the purposes of this study, as described above. If you do not want to authorize the use of this PHI, you should not agree to be in this study.

☐ I have read this consent form or ☐ it was read to me by: _____.

Any questions I had were answered by: _____.

I ☐ am ☐ am not participating in another research project at this time.
(If yes, you should discuss this with your study doctor.)

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I voluntarily agree to participate in this research program at:

☐ Program for In Vitro Fertilization, Reproductive Surgery and Infertility

I understand that I am entitled to and will be given a copy of this signed Consent/Authorization Form. By signing this Consent/Authorization form, I give my Authorization for the uses and disclosures of my protected health information as described above.

WHEN THE SUBJECT IS AN ADULT:

Notice Concerning HIV-Related Information : If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.

* For subjects who may not be capable of providing informed consent, the signature of a legal representative is required. For a valid HIPAA authorization, the "personal representative" must have authority under state law to make health care decisions for the subject.

Menachem Grossman
Print Name of Participants or Legal Representatives*

Signature of Participants or Legal Representatives*

7/19/04
Date

Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent

7/19/04
Date

** When the elements of informed consent are presented orally to the subject or representative, a witness to the oral presentation is required.

Print Name of Witness**

Signature of Witness**

Date

Subject's Initials: CKG MMG Date: 7/19/04

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